

EPA Reg. No. 11678-57
Volume 4

Material Sent for Data Extraction

Reg. # 11678-57

Description: Addition of 21 Day Content Screen Review and Application Materials

☐ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated 2-8-12

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☒ Other: _____

☐ Decision #: 430430

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Jennifer Haines

Phone: 305-5967 Division: RD

Date: 2/22/12

Material Sent for Data Extraction

Reg. # 111678-57

Description: New Tech Label Adding Residential + Food Handling Uses

☐ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 2-8-2012

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☐ Other: _____

☐ Decision #: D-430430

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Jennifer Haines

Phone: 305-5967 Division: PD

Date: 2/15/2012

NOTE TO FILE
EPA REG. NO. 11678-57

The PRIA date for action (D430430) was missed by eight (8) days. Potential issues of concern were raised by the Office Director after completion of the public process. Staff needed additional days to rewrite the final decision document and receive approval to register the new use.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Bert Volger, Ph.D.
Makhteshim Agan of North America, Inc.
4515 Falls of Neuse Rd., Suite 300
Raleigh, NC 27609

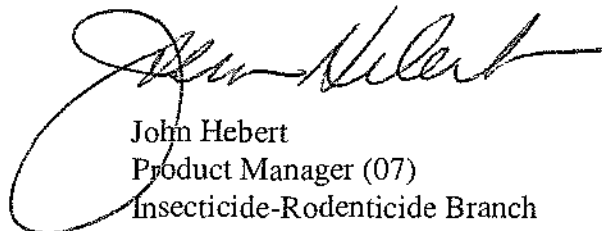
FEB 08 2012

Dear Dr. Volger:

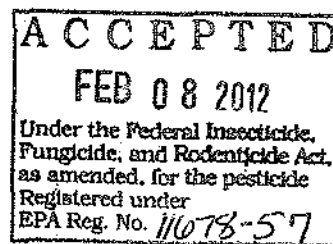
Subject: Label Amendment to Rimon Technical Adding Food
Handling Establishments and Residential Uses
EPA Registration No. 11678-57
Submission Date: March 16, 2010
OPP Decision Number: D-430430

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records. Please submit one (1) final printed copy for the above mentioned label before releasing the product for shipment. If you have any questions regarding this label, please contact Jennifer Gaines at (703) 305-5967 or via e-mail at gaines.jennifer@epa.gov.

Sincerely yours,



John Hebert
Product Manager (07)
Insecticide-Rodenticide Branch
Registration Division (7505P)



TECHNICAL

(Novaluron)

For The Manufacture of Insecticides Only

ACTIVE INGREDIENT: Novaluron:

% BY WT.

1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]-

3-(2,6-difluorobenzoyl)urea..... 98.5%

OTHER INGREDIENTS: 1.5%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact PROSAR at 1-877-250-9291 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters except in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

NET CONTENTS 55 POUNDS



Manufactured for:
Makhteshim Chemical Works, Ltd.
c/o Makhteshim-Agan of North America, Inc.
3120 Highlands Blvd, Suite 100
Raleigh, NC 27604
919-256-8305

EPA Reg. No. 11678-57
EPA Est. No. 11678-ISR-002

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This pesticide is for the further manufacture of formulated insecticides only. Formulators using this product are responsible for obtaining EPA registration for their formulated products.

Only for formulation into an insecticide for the following uses:

(1) Beans (snap, dry); Berries (low-growing), including cranberry, lingonberry, muntries, partridgeberry, bearberry, bilberry, lowbush blueberry, cloudberry; Bushberries, including: blueberry (highbush and lowbush), currant, elderberry, gooseberry, and huckleberry; Cotton; Cucurbit vegetables, including balsam apple, balsam pear, chayote (fruit) cantaloupe, cucumber, chinese cucumber, gherkin (west indian), edible gourd, melon, citron melon, muskmelon, bittermelon, pumpkin, squash, summer squash, winter squash, watermelon and chinese waxgourd; Fruiting vegetables (field grown), including tomatoes (including bush, currant and tree tomatoes), peppers, eggplants (including african, pea and scarlet eggplants), tomatillo, groundcherry, pepino, okra, cocona, goji berry, garden huckleberry, marlynia, naranjilla, roselle, and sunberry; Head and stem brassica vegetables including: broccoli, chinese broccoli, brussel sprouts, cabbage, cavalo broccolo, cauliflower, chinese broccoli (gai lon), chinese cabbage (napa), chinese mustard (gai choy), and kohlrabi; Leafy brassica greens, including: broccoli raab, chinese cabbage (bok choy), collards, kale, mizuna, mustard greens, mustard spinach, and rape greens; Ornamentals (container grown ornamentals in green-houses, shade-houses, and outdoor nurseries); Pome fruit; Potatoes/ sweet potatoes; Stone fruits, including apricots, cherries (sweet and tart), nectarines, peaches, plums and prune plums; sorghum; strawberry; sugarcane; sweet corn; Swiss chard; Turnip greens.

(2) Domestic and Non-Domestic Indoor and Outdoor.

(3) Food and Nonfood Areas of Food Handling Establishments.

(4) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and

(5) Uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

CONTAINER HANDLING:

Liner: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities.

Drum: Refillable container. Refill this container with novaluron only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. If drum is contaminated and can not be reused, dispose of in a sanitary landfill or by incineration if allowed by State and local authorities.

LIMITATION OF WARRANTY AND LIABILITY

Read the entire directions for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES and LIMITATIONS OF LIABILITY.**

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Makhteshim Chemical Works, Ltd. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Makhteshim Chemical Works, Ltd. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Makhteshim Agan of North America, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Makhteshim Chemical Works, Ltd. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in

contract, warranty, tort, negligence, strict liability or otherwise, shall not exclude the purchase price paid or at Makhteshim Chemical Works, Ltd.'s election, the replacement of product.

Copyright 2002

RIMON[®] is a registered trademark of Makhteshim Chemical Works Ltd.

Rimon Technical (11678-57); (EPA approved 09-30-2011), revised 1-31-2012



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

*File
2011*

September 13, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
OR PAY ON-LINE at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-454533
EPA File Symbol or Registration Number: 11678-57
Product Name: RIMON TECHNICAL
EPA Receipt Date: 13-Sep-2011
EPA Company Number: 11678
Company Name: MAKHTESHIM CHEMICAL WORKS LTD

Bert Volger
MAKHTESIM-AGAN OF NORTH AMERICA, INC.
MAKHTESHIM CHEMICAL WORKS LTD
4515 FALLS OF NEUSE RD, SUITE 300
RALEIGH, NC 27609-

SUBJECT: Receipt of Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for Amendment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R230

NEW USE;OUTDOOR;NON-FOOD;

Please remit payment in the amount of: \$ 23,969 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 979074
St. Louis, MO 63197

By Courier:
U.S. Bank
Government Lockbox 979074
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63197
Tephone: (314) 418-4990

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

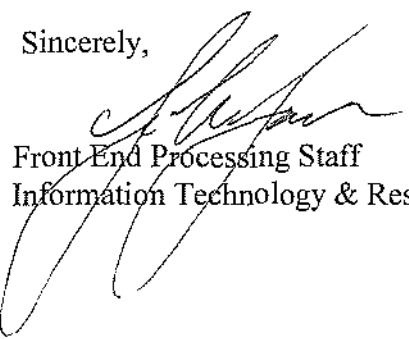
By USPS:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

By Courier:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900 Potomac Yard
2777 S. Crystal Dr.
Arlington, VA

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 14 days, the Agency will presume that you no longer want to pursue this action. The Agency will then reject your application and issue an invoice for any applicable outstanding fees.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 308-9362.

Sincerely,



Front End Processing Staff
Information Technology & Resources Management Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

*File
evk*

September 13, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
OR PAY ON-LINE at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-454534
EPA File Symbol or Registration Number: 11678-57
Product Name: RIMON TECHNICAL
EPA Receipt Date: 13-Sep-2011
EPA Company Number: 11678
Company Name: MAKHTESHIM CHEMICAL WORKS LTD

Bert Volger
MAKHTESIM-AGAN OF NORTH AMERICA, INC.
MAKHTESHIM CHEMICAL WORKS LTD
4515 FALLS OF NEUSE RD, SUITE 300
RALEIGH, NC 27609-

SUBJECT: Receipt of Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for Amendment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R260

NEW USE;NON-FOOD;INDOOR;

Please remit payment in the amount of: \$ 11,577 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 979074
St. Louis, MO 63197

By Courier:
U.S. Bank
Government Lockbox 979074
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63197
Tephone: (314) 418-4990

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

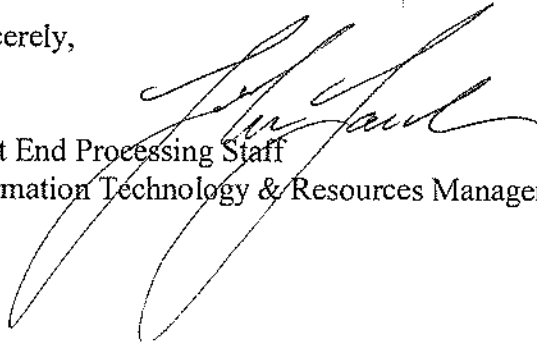
By Courier:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900 Potomac Yard
2777 S. Crystal Dr.
Arlington, VA

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 14 days, the Agency will presume that you no longer want to pursue this action. The Agency will then reject your application and issue an invoice for any applicable outstanding fees.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 308-9362.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

A large, stylized handwritten signature in black ink, written over the typed text.

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 3-19-10

Experts In-Processing Signature: MF HARRINGTON Date 3-24-10 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>11678-57</u>		EPA Receipt Date: <u>3-19-10</u>				
Items for Review			Yes	No	N/A*	
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form) a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)			yes	no	X
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)			yes	no	
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack) a) Selective Method (Fee category experts use) b) Cite-All (Fee category experts use) c) Applicant owns all data (Fee category experts use)			yes	no	X
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

KC D Studies associated w/ Juckett (MRID 480249) have passed B6-E review

Pass

MRID 480349

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses even if a product is currently registered by consulting the inert Web

site [link to <http://www.epa.gov/oppr001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/oppr001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 23, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-430430
EPA File Symbol or Registration Number: 11678-57
Product Name: RIMON TECHNICAL
EPA Receipt Date: 19-Mar-2010
EPA Company Number: 11678
Company Name: MAKHTESHIM CHEMICAL WORKS LTD

EPHI GUR
MAKHTESIM-AGAN OF NORTH AMERICA, INC.
MAKHTESHIM CHEMICAL WORKS LTD
4515 FALLS OF NEUSE RD, SUITE 300
RALEIGH, NC 27609-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R140

NEW USE;INDOOR FOOD/FOOD HANDLING;ADDITIONAL FOOD USE;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-6249.

Sincerely,

A handwritten signature in cursive script, reading "Teresa Downs", is positioned above the typed name.

Front End Processing Staff

Information Technology & Resources Management Division

Fee for Service

W
{8702575~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☐ Fee Waiver?
☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 7

Receipt No.

S- 870257

EPA File Symbol/Reg. No.

11678-57

Pin-Punch Date:

3/19/2010

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R140

Granted: R140

Amount Due: \$ 38,588.⁰⁰

Parent/Child Decisions:

petition GF7708

End-use

66222-ERT

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: He Bo D

Date: 3/23/10

Remarks:

Receipt for Section 3

S: 870257

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 11678 MAKHTESHIM CHEMICAL WORKS LTD

V

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 7

Product #: 11678-57 Product Name: RIMON TECHNICAL

Override#:

Me Too

Me Too

Section3:

Product Name:

Application Date: 16-Mar-2010

OPP Rec'd Date: 19-Mar-2010

Front End Date: 22-Mar-2010

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track:

New Ingredient:

Receipt Description:

Application for registration amendment; add new uses

New Ingredient:

Request Date:

New Ingredient:

Received Date:

Form A:

Signature Date:

Form B:

Signature Date:

Receipt Content

Des

Study

Paper Label

View/Edit

RE: Proof of PRIA fee payment needed for amendment to Rimon Technical (EPA reg. no. 11678-57)
Bert Volger
to:
Teresa Downs
03/23/2010 11:15 AM
Show Details

Hi Teresa,

I copied the confirmation of the subject PRIA fee into this e-mail (see below).

Please let me know, if you need any further info.

Thanks,
Bert

From: paygovadmin@mail.doc.twai.gov [paygovadmin@mail.doc.twai.gov]
Sent: Thursday, March 18, 2010 1:22 PM
To: Annie Stout
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Transaction Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 250HS6C7
Agency Tracking ID: 74106935688

Name On Account: Makhteshim Agan of North America Transaction Type: ACH Debit Transaction
Amount: \$38,588.00 Payment Date: Mar 19, 2010 Account Type: Business Checking Routing Number:
026002794 Account Number: *****7618

Transaction Date: Mar 18, 2010 2:22:21 PM Number of Payments Scheduled: 1
Frequency: OneTime
Decision Number:
Registration Number: 11678-57
Company Name: Makhteshim Chemical Works
Company Number: 11678
Action Code: R140=

-----Original Message-----

From: Downs.Teresa@epamail.epa.gov [mailto:Downs.Teresa@epamail.epa.gov]
Sent: Tuesday, March 23, 2010 11:03 AM
To: bertvolger@comcast.net
Subject: Proof of PRIA fee payment needed for amendment to Rimon Technical (EPA



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11678-57	2. EPA Product Manager Kable Bo Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) RIMON TECHNICAL	PM# 07	
5. Name and Address of Applicant (Include ZIP Code) Makhteshim Chemical Works c/o Makhteshim Agan of North America, Inc. 4515 Falls of Neuse Rd, Suite 300 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Ma Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Additional Food Use; indoor; Food/Food Handling
FEE CATEGORY: R140: 15 months review process
FEE OUE: \$ 38,588
EMAIL: bertvolger@comcast.net

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Bert Volger	Title Consultant for MANA	Telephone No. (Include Area Code) 610-793-3222
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Consultant for MANA	
4. Typed Name Bert Volger	5. Date 03/16/2010	



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401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Makhteshim Chemical Works, 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609	EPA Registration Number/File Symbol 11678-57
Active Ingredient(s) and/or representative test compound(s) Novaluron	Date March 16, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial and Aquatic Food, Terrestrial Non-Food, Domestic and Non-Domestic In-Door and Out-Door	Product Name RIMON TECHNICAL

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 03/16/2010	Typed or Printed Name and Title Bert Volger Ph.D., Consultant to MCW
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DATA MATRIX

Date: March 16, 2010	EPA Reg. No./File Symbol: 11678-57	Page of 18
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609		Product: RIMON® Technical

Ingredient: Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Physical and Chemical Properties:					
158.155 (OPPTS 830.1550)	"Rimon" (Novaluron) Product Chemistry Data: Product Identity and Disclosure of Ingredients, Description of Beginning Material and Manufacturing, and Discussion of Formation of Impurities.	44961003	Makhteshim-Agan of North America Inc.	OWN	
158.160 (OPPTS 830.1600)	"Rimon" (Novaluron) Product Chemistry Data: Product Identity and Disclosure of Ingredients, Description of Beginning Material and Manufacturing, and Discussion of Formation of Impurities.	44961003	Makhteshim-Agan of North America Inc.	OWN	
158.162 (OPPTS 830.1620)	"Rimon" (Novaluron) Product Chemistry Data: Product Identity and Disclosure of Ingredients, Description of Beginning Material and Manufacturing, and Discussion of Formation of Impurities.	44961003	Makhteshim-Agan of North America Inc.	OWN	
158.165 (OPPTS 830.1650)	"Rimon" (Novaluron) Product Chemistry Data: Product Identity and Disclosure of Ingredients, Description of Beginning Material and Manufacturing, and Discussion of Formation of Impurities.	44961003	Makhteshim-Agan of North America Inc.	OWN	
158.167 (OPPTS 830.1670)	"Rimon" (Novaluron) Product Chemistry Data: Product Identity and Disclosure of Ingredients, Description of Beginning Material and Manufacturing, and Discussion of Formation of Impurities.	44961003	Makhteshim-Agan of North America Inc.	OWN	
158.170 (OPPTS 830.1700)	Rimon-Quantification of Active Ingredient and Impurities present at or above 0.1% in technical Rimon (FIFRA Guideline-Series 62)	44961004	Makhteshim-Agan of North America Inc.	OWN	
158.175 (OPPTS 830.1750)	Rimon-Quantification of Active Ingredient and Impurities present at or above 0.1% in technical Rimon (FIFRA Guideline-Series 62)	44961004	Makhteshim-Agan of North America Inc.	OWN	
158.180 (OPPTS 830.1800)	Rimon-Quantification of Active Ingredient and Impurities present at or above 0.1% in technical Rimon (FIFRA Guideline-Series 62)	44961004	Makhteshim-Agan of North America Inc.	OWN	
64-1 (OPPTS 830.1900)	Submittal of samples	NA	Makhteshim-Agan of North America Inc.	OWN	
63-2 (OPPTS 830.6302)	Rimon Technical: Determination of the physico-chemical properties. GLP, Unpublished	44961007	Makhteshim-Agan of North America Inc.	OWN	
63-2 (OPPTS 830.6302)	Rimon (Pure): Determination of the physico-chemical properties.	44961006	Makhteshim-Agan of North America Inc.	OWN	
63-3 (OPPTS 830.6303)	Rimon Technical: Physical State; Stability; pH; and solubility.	44961005	Makhteshim-Agan of North America Inc.	OWN	

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DATA MATRIX

Date: March 16, 2010	EPA Reg. No./File Symbol: 11678-57	Page of 18
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609	Product: RIMON® Technical	

Ingredient: Novaluron

Guideline Reference Number	Guideline Study Name	MRIO Number	Submitter	Status	Note
			Inc.		
63-4 (OPPTS 830.6304)	Rimon Technical: Determination of the physico-chemical properties. GLP, Unpublished	44961007	Makhteshim-Agan of North America Inc.	OWN	
63-4 (OPPTS 830.6304)	Rimon (Pure): Determination of the physico-chemical properties.	44961006	Makhteshim-Agan of North America Inc.	OWN	
63-5 (OPPTS 830.7200)	Rimon (Pure): Determination of the physico-chemical properties.	44961006	Makhteshim-Agan of North America Inc.	OWN	
63-6 (OPPTS 830.7220)	Boiling point/boiling range	NA	NA	NA	Not required
63-7 (OPPTS 830.7300)	Rimon (Pure): Determination of the physico-chemical properties.	44961006	Makhteshim-Agan of North America Inc.	OWN	
63-8 (OPPTS 830.7840)	Rimon Technical: Determination of the physico-chemical properties. GLP, Unpublished	44961007	Makhteshim-Agan of North America Inc.	OWN	
63-8 (OPPTS 830.7840)	275-352 I: Water solubility	Not assigned yet	Makhteshim-Agan of North America Inc.	OWN	
63-8 (OPPTS 830.7860)	Rimon Technical: Determination of the physico-chemical properties. GLP, Unpublished	44961007	Makhteshim-Agan of North America Inc.	OWN	
63-8 (OPPTS 830.7860)	275-352 I: Water solubility	45651501	Makhteshim-Agan of North America Inc.	OWN	
63-9 (OPPTS 830.7950)	Rimon (Pure): Determination of the physico-chemical properties.	44961006	Makhteshim-Agan of North America Inc.	OWN	
63-10 (OPPTS 830.7370)	Rimon Technical: Color, Odor, UV/Vis Absorption, Melting point, Density, Dissociation Constant, Partition Coefficient (Octanol / water), Solubility, and Vapor Pressure.	44961006	Makhteshim-Agan of North America Inc.	OWN	
63-11 (OPPTS 830.7550)	Rimon (Pure): Determination of the physico-chemical properties.	44961006	Makhteshim-Agan of North America Inc.	OWN	
					28

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Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: March 16, 2010

EPA Reg. No./File Symbol: 11678-57

Page of 18

Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc.
 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609

Product: RIMON® Technical

Ingredient: Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-12 (OPPTS 830.7000)	Rimon Technical: Physical State; Stability; pH; and solubility.	44961005	Makhteshim-Agan of North America Inc.	OWN	
63-13 (OPPTS 830.6313)	Rimon Technical: Physical State; Stability; pH; and solubility.	44961005	Makhteshim-Agan of North America Inc.	OWN	
63-14 (OPPTS 830.6314)	Oxidation/reduction: chemical incompatibility	NA	NA	NA	Not required
63-15 (OPPTS 830.6315)	Rimon Technical: Determination of the physico-chemical properties. GLP, Unpublished	44961007	Makhteshim-Agan of North America Inc.	OWN	
63-16 (OPPTS 830.6316)	Rimon Technical: Determination of the physico-chemical properties. GLP, Unpublished	44961007	Makhteshim-Agan of North America Inc.	OWN	
63-17 (OPPTS 830.6317)	Comb. A. (2003) "Rimon" (Technical Grade) Storage Stability. Project Number: MAK/760, R/14502, MAK760/032350.	46086201	Makhteshim-Agan of North America Inc.	OWN	
63-18 (OPPTS 830.6318)	Viscosity	NA	NA	NA	Not required
63-19 (OPPTS 830.7100)	Miscibility	NA	NA	NA	Not required
63-20 (OPPTS 830.6320)	Corrosion Characteristics	NA	NA	NA	Not required
63-21 (OPPTS 830.6321)	Dielectric breakdown voltage	NA	NA	NA	Not required
NONE (OPPTS 830.7050)	Rimon (Pure): Determination of the physico-chemical properties.	44961006	Makhteshim-Agan of North America Inc.	OWN	



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DATA MATRIX

Date: March 16, 2010			EPA Reg. No./File Symbol: 11678-57	Page of 18	
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609			Product: RIMON® Technical		
Ingredient: Novaluron					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<u>Residue Chemistry:</u>					
171-2 (OPPTS 860.1100)	"Rimon" (Novaluron) Product Chemistry Data: Product Identity and Disclosure of Ingredients, Description of Beginning Material and Manufacturing, and Discussion of Formation of Impurities.	44961003	Makhteshim-Agan of North America Inc.	OWN	
171-3 (OPPTS 860.1200)	Directions for use	NA	Makhteshim-Agan of North America Inc.	OWN	See attached Product Label
171-4 (OPPTS 860.1300)	¹⁴ C "RIMON": Metabolism in apples.	45638226	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1300)	¹⁴ C "RIMON": Metabolism in cabbages.	45638227	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1300)	¹⁴ C "RIMON": Metabolism in potatoes.	45771803	Makhteshim-Agan of North America Inc.	OWN	

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DATA MATRIX

Date: March 16, 2010			EPA Reg. No./File Symbol: 11678-57		Page of 18
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609			Product: RIMON® Technical		
Ingredient: Novaluron					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
171-4 (OPPTS 860.1300)	¹⁴ C-"RIMON": Metabolism in cotton.	45638302	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1300)	¹⁴ C "RIMON" Metabolism in the lactating goat.	45638303	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1340)	Development and validation of an analytical method for the determination of Rimon in apples, cabbages and potatoes	45638304	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1340)	Radiovalidation of Residue Method for the Determination of Novaluron in Cotton. Project Number: 1122W/1, 1122W, 2002/020.	46714901	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1340)	Independent Validation of the Analytical Method for Novaluron (Rimon) in Apples.	45638305	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1340)	Independent Validation (ILV) of an HPLC/UV Based Analytical Method for the Determination Novaluron in Cotton.	45638306	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1340)	The development and validation of methodology for the determination of RIMON residues in Bovine tissues (fat, kidney, liver, muscle), milk and eggs	45638307	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1340)	Radiovalidation of Analytical Method for Determination of Novaluron in Bovine Tissues. Project Number: MAK/797, MAK/797/032011, 2002/119.	46714902	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1340)	Determination of Novaluron in Sorghum Agricultural and Processing Commodities by LC-MS/MS. Project Number: 189, MANA/07102008. Unpublished study prepared by Morse Laboratories, Inc. 45 p.	47486302	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1340)	Novaluron: Independent laboratory validation (ILV) of methodology for the post-registration monitoring of residues of Novaluron in milk, muscle and liver.	45638308	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1380)	Storage stability: Magnitude of the Residue of Novaluron in Pome Fruit Raw Agricultural and Processed Commodities and Magnitude of the Residue of Novaluron in Cotton Raw Agricultural	45638420	Makhteshim-Agan of North America Inc.	OWN	Magnitude of the residue studies included storage

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DATA MATRIX

Date: March 16, 2010		EPA Reg. No./File Symbol: 11678-57		Page of 18	
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609		Product: RIMON® Technical			
Ingredient: Novaluron					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	and Processed Commodities				stability testing.
171-4 (OPPTS 860.1400)	Development and validation of an analytical method for the determination of Rimon in groundwater.	45638309	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1400)	Novaluron: Development and validation of methodology for the determination of residues of Novaluron and its chlorophenyl urea metabolite (275-352 I) in drinking water, ground water and surface water.	45638310	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1400)	Residues in fish	NA	NA	NA	Not required
171-4 (OPPTS 860.1400)	Residues in irrigated crops	NA	NA	NA	Not required
171-4 (OPPTS 860.1460)	Residues from food handling	NA	NA	NA	Not required
171-4 (OPPTS 860.1480)	"RIMON" Technical: Residues in milk and tissues of dairy cows	45638311	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1480)	"RIMON" Technical: Residue transfer study – accumulation and depletion of residues in eggs and tissues of laying hens. Project No. MAK/0900/062531, Makhteshim Chemical Works Ltd., Report No R-18701, plus supplemental information	46870601, 47486301	Makhteshim-Agan of North America Inc.	OWN	
171-13 (OPPTS 860.1650)	Submittal of analytical reference standards	NA	NA	NA	Previously submitted (2001)
165-1 (OPPTS 860.1850)	14C-"RIMON": Accumulation in confined rotational crops. Huntingdon Life Sciences Ltd., UK, Report No. MAK559/002865. Makhteshim Chemical Works Ltd., Report No. R-11236	45638312	Makhteshim-Agan of North America Inc.	OWN	
165-2 (OPPTS 860.1900)	Rotational Crop Study: Novaluron treated mustard greens rotated with turnips and wheat	47180502	Makhteshim-Agan of North America Inc.	OWN	



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DATA MATRIX

Date: March 16, 2010	EPA Reg. No./File Symbol 11678-57	Page of 18
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609		Product: RIMON® Technical

Ingredient Novaturon

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Environmental Fate:					
161-1 (OPPTS 835.2120)	¹⁴ C "RIMON": Hydrolysis under laboratory conditions	44961008	Makhteshim-Agan of North America Inc.	OWN	
161-2 (OPPTS 835.2240)	¹⁴ C "RIMON": Photolytic degradation in water	45638203	Makhteshim-Agan of North America Inc.	OWN	
161-3 (OPPTS 835.2410)	¹⁴ C "RIMON": Photodegradation on soil...	45638204	Makhteshim-Agan of North America Inc.	OWN	
161-4 (OPPTS 835.2370)	Rimon (Pure): Determination of the physico-chemical properties	44961006	Makhteshim-Agan of North America Inc.	OWN	
162-1 (OPPTS 835.4100)	¹⁴ C - "RIMON": Aerobic Soil Metabolism (Pilot study).	44961010	Makhteshim-Agan of North America Inc.	OWN	
162-1 (OPPTS 835.4100)	¹⁴ C-"RIMON": Aerobic soil metabolism (Route of Degradation)	44961009	Makhteshim-Agan of North America Inc.	OWN	
162-1 (OPPTS 835.4100)	¹⁴ C-"RIMON": Aerobic soil rate of degradation	44961009	Makhteshim-Agan of North America Inc.	OWN	
162-2 (OPPTS 835.4200)	¹⁴ C-"RIMON": Anaerobic soil metabolism	45638205	Makhteshim-Agan of North America Inc.	OWN	
162-3 (OPPTS 835.4400)	Anaerobic Aquatic Metabolism of ¹⁴ C "RIMON"	45638207	Makhteshim-Agan of North America Inc.	OWN	
162-4 (OPPTS 835.4300)	¹⁴ C-"Rimon": Degradability and fate in the water/sediment system	45638206	Makhteshim-Agan of North America Inc.	OWN	
163-1 (OPPTS 835.1230)	¹⁴ C "RIMON": Adsorption/desorption on soil	44961012	Makhteshim-Agan of North America Inc.	OWN	
163-1 (OPPTS 835.1230)	¹⁴ C-275-352 I: Adsorption/desorption on soil	45638201	Makhteshim-Agan of North America Inc.	OWN	
163-1 (OPPTS 835.1240)	¹⁴ C- "RIMON": Soil column leaching	44961011	Makhteshim-Agan of North America Inc.	OWN	
					33



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DATA MATRIX

Date: March 16, 2010	EPA Reg. No./File Symbol 11678-57	Page of 18
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609		Product: RIMON® Technical

Ingredient Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
163-2	Volatility (Lab)	NA	NA	NA	Not required
163-3	Volatility (Field)	NA	NA	NA	Not required
164-1 (OPPTS 835.6100)	Terrestrial Field Soil Dissipation of Novaluron. American Agricultural Services, Inc. Cary, N.C	45789204	Makhteshim-Agan of North America Inc.	OWN	
164-2 (OPPTS 835.6200)	Dissipation – Aquatic sediment (field)	NA	NA	NA	Not required
164-3 (OPPTS 835.6300)	Dissipation – Forestry (field)	NA	NA	NA	Not required
164-4 (OPPTS 835.6400)	Dissipation – Combination and tank mixes (field)	NA	NA	NA	Not required
164-5 (OPPTS 835.6500)	Dissipation -- Soil, long-term	NA	NA	NA	Not required
165-1 (OPPTS 860.1850)	¹⁴ C-"RIMON": Accumulation in confined rotational crops.	45638312	Makhteshim-Agan of North America Inc.	OWN	
165-2 (OPPTS 860.1900)	Accumulation –crops	NA		NA	Not required
165-3	Accumulation studies – irrigated crops	NA	NA	NA	Not required
165-4 (OPPTS 850.1730)	¹⁴ C-"RIMON": Bioconcentration in Bluegill sunfish	45638215	Makhteshim-Agan of North America Inc.	OWN	

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DATA MATRIX

Date: March 16, 2010

EPA Reg. No./File Symbol 11678-57

Page of 18

Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc.
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Product: RIMON® Technical

Ingredient Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Health Effects:					
81-1 (OPPTS 870.1100)	GR 572: Acute oral toxicity (LD ₅₀) in rats Inveresk.	44961001	Makhteshim-Agan of North America Inc.	OWN	
81-2 (OPPTS 870.1200)	Acute dermal toxicity to rats of GR 572 Tech	45003201	Makhteshim-Agan of North America Inc.	OWN	
81-3 (OPPTS 870.1300)	GR 572 Tech: Acute inhalation toxicity study in rats (Limit test)	45003202	Makhteshim-Agan of North America Inc.	OWN	
81-4 (OPPTS 870.2400)	Irritant effects on the rabbit eye of GR 572 Tech	45003203	Makhteshim-Agan of North America Inc.	OWN	
81-5 (OPPTS 870.2500)	Irritant effects on rabbit skin of GR 572 Tech	45003204	Makhteshim-Agan of North America Inc.	OWN	
81-6 (OPPTS 870.2600)	Skin sensitization test in Guinea Pigs of the test article GR 572 tech	44961002	Makhteshim-Agan of North America Inc.	OWN	
81-6 (OPPTS 870.2600)	RIMON® Technical - Skin sensitisation in the guinea-pig (incorporating a positive control using hexyl cinnamic aldehyde)	45084001	Makhteshim-Agan of North America Inc.	OWN	
81-7 (OPPTS 870.6100)	Acute delayed neurotoxicity - hen	NA	NA	NA	Not required
81-8 (OPPTS 870.6200)	RIMON Technical: Neurotoxicity study by a single oral gavage administration to CD rats followed by a 14-day observation period.	45082601	Makhteshim-Agan of North America Inc.	OWN	
NONE (OPPTS 870.3050)	GR 572 (Technical): Toxicity to rats by dietary administration for 4 weeks.	45638313	Makhteshim-Agan of North America Inc.	OWN	



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DATA MATRIX

Date: March 16, 2010	EPA Reg. No./File Symbol 11678-57	Page of 18
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609		Product: RIMON® Technical

Ingredient Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
81-8 (OPPTS 870.6200)	RIMON Technical: Neurotoxicity study by a single oral gavage administration to CD rats followed by a 14-day observation period.	45082601	Makhteshim-Agan of North America Inc.	OWN	
NONE (OPPTS 870.3050)	GR 572 (Technical): Toxicity to rats by dietary administration for 4 weeks.	45638313	Makhteshim-Agan of North America Inc.	OWN	
82-1 (OPPTS 870.3100)	"RIMON" Technical: Toxicity study by dietary administration to CD-1 Mice for 13 weeks followed by an 8 week reversibility period.	45651502	Makhteshim-Agan of North America Inc.	OWN	
82-1 (OPPTS 870.3100)	GR 572 (Technical): Toxicity to rats by dietary administration for 13 weeks.	45651503	Makhteshim-Agan of North America Inc.	OWN	
82-1 (OPPTS 870.3100)	GR 572 tech.: 13-week oral toxicity study in rats	45651504	Makhteshim-Agan of North America Inc.	OWN	
82-1 (OPPTS 870.3100)	Rimon Technical: Toxicity study by dietary administration to CD rats for 13 weeks Followed by a 4 week reversibility period.	45030001	Makhteshim-Agan of North America Inc.	OWN	
82-1 (OPPTS 870.3150)	"RIMON" Technical: Toxicity study by oral capsule administration to beagle dogs for 52 weeks.	45638320	Makhteshim-Agan of North America Inc.	OWN	
82-2 (OPPTS 870.3200)	"RIMON" Technical: Toxicity study by dermal administration to CD rats for 4 weeks.	45288501	Makhteshim-Agan of North America Inc.	OWN	
82-3 (OPPTS 870.3250)	90 day dermal	NA	NA	NA	Not required
82-4 (OPPTS 870.3465)	90 day inhalation – rat	NA	NA	NA	Not required
82-5	"Rimon" Technical: Neurotoxicity Study by Dietary Administration to CD Rats for 13 Weeks. Project Number: MAK/759/023152, R/14518, MAK/759.	46086204	Makhteshim-Agan of North America Inc.	OWN	
83-1 (OPPTS 870.4100)	"RIMON" Technical: Combined carcinogenicity and toxicity study by dietary administration to CD rats for 104 weeks...	45651506	Makhteshim-Agan of North America Inc.	OWN	36



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DATA MATRIX

Date: March 16, 2010

EPA Reg. No./File Symbol 11678-57

Page of 18

Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc.
 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609

Product: RIMON® Technical

Ingredient Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-2 (OPPTS 870.4200)	"RIMON" Technical: Carcinogenicity study by dietary administration to CD-1 mice for 78 weeks...	45651507	Makhteshim-Agan of North America Inc.	OWN	
83-3 (OPPTS 870.3700)	"RIMON" Technical: Preliminary study of embryo-foetal toxicity study in CD the rat by oral gavage administration...	45638315	Makhteshim-Agan of North America Inc.	OWN	
83-3 (OPPTS 870.3700)	"RIMON" Technical: Study of embryo-foetal toxicity in the CD rat by oral gavage administration...	45082602	Makhteshim-Agan of North America Inc.	OWN	
83-3 (OPPTS 870.3700)	Rimon Technical: Study of tolerance in the rabbit by oral gavage administration...	45638316	Makhteshim-Agan of North America Inc.	OWN	
83-3 (OPPTS 870.3700)	"RIMON" Technical: Preliminary embryo-foetal toxicity study in the rabbit by oral gavage administration...	45638317	Makhteshim-Agan of North America Inc.	OWN	
83-3 (OPPTS 870.3700)	"RIMON" Technical: Study of embryo-fetal toxicity in the rabbit by oral gavage administration...	45638318	Makhteshim-Agan of North America Inc.	OWN	
83-4 (OPPTS 870.3800)	"RIMON" Technical: Preliminary study of effects on reproductive performance in CD rats by dietary administration...	45638319	Makhteshim-Agan of North America Inc.	OWN	
83-4 (OPPTS 870.3800)	"RIMON" Technical: Study of reproductive performance in CD rats treated continuously through two successive generations by dietary administration...	45651505	Makhteshim-Agan of North America Inc.	OWN	
83-5 (OPPTS 870.4300)	"RIMON" Technical: Combined carcinogenicity and toxicity study by dietary administration to CD rats for 104 weeks...	45651506	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5100)	RIMON Technical: Bacterial mutation assay	44961013	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5140)	RIMON Technical: Bacterial mutation assay	44961013	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5250)	RIMON Technical: Bacterial mutation assay	44961013	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5195)	In vitro assessment of the clastogenic activity of GR 572 in cultured human lymphocytes.	44961015	Makhteshim-Agan of North America Inc.	OWN	37



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Date: March 16, 2010

EPA Reg. No./File Symbol 11678-57

Page of 18

Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc.
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Product: RIMON® Technical

Ingredient Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
84-2 (OPPTS 870.5200)	<u>In vitro</u> assessment of the clastogenic activity of GR 572 in cultured human lymphocytes.	44961015	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5300)	<u>In vitro</u> assessment of the clastogenic activity of GR 572 in cultured human lymphocytes.	44961015	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5275)	GR 572 (FCF/T/46): Testing for mutagenic activity with <i>Salmonella typhimurium</i> TA 1535, TA 1537, TA 1538, TA 98 and TA 100 Inveresk.	45030003	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5450)	GR 572 (FCF/T/46): Testing for mutagenic activity with <i>Salmonella typhimurium</i> TA 1535, TA 1537, TA 1538, TA 98 and TA 100 Inveresk.	45030003	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5460)	GR 572 (FCF/T/46): Testing for mutagenic activity with <i>Salmonella typhimurium</i> TA 1535, TA 1537, TA 1538, TA 98 and TA 100 Inveresk.	45030003	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5300)	An assessment of the mutagenic potential of GR 572 using the mouse lymphoma TK Locus Assay.	45638321	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5395)	Mouse micronucleus test on GR 572.	45638322	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5550)	"RIMON" Technical: Bacterial DNA repair (<i>rec</i>) assay.	44961014	Makhteshim-Agan of North America Inc.	OWN	



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DATA MATRIX

Date: March 16, 2010			EPA Reg. No./File Symbol 11678-57	Page of 18	
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609			Product: RIMON® Technical		
Ingredient Novaluron					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
84-2 (OPPTS 870.5575)	"RIMON" Technical: Bacterial DNA repair (<i>rec</i>) assay.	44961014	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5500)	Assessment of unscheduled DNA repair synthesis in mammalian cells after exposure to GR 572.	45030002	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5550)	Assessment of unscheduled DNA repair synthesis in mammalian cells after exposure to GR 572.	45030002	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5575)	Assessment of unscheduled DNA repair synthesis in mammalian cells after exposure to GR 572.	45030002	Makhteshim-Agan of North America Inc.	OWN	
84-4	Other genotoxic effects	NA	NA	NA	Not required
85-1 (OPPTS 870.7485)	¹⁴ C-"RIMON": Metabolism in the rat (Pilot Study)	45638323	Makhteshim-Agan of North America Inc.	OWN	
85-1 (OPPTS 870.7485)	¹⁴ C-"RIMON": Metabolism in the rat	45638401	Makhteshim-Agan of North America Inc.	OWN	
85-2 (OPPTS 870.7600)	Dermal penetration	NA	NA	NA	Not required
86-1	Domestic animal safety	NA	NA	NA	Not required

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DATA MATRIX

Date: March 16, 2010		EPA Reg. No./File Symbol 11678-57		Page of 18	
Applicant's/Registrants Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609		Product: RIMON® Technical			
Ingredient Novaluron					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Ecological Effects:					
71-1 (OPPTS 850.2100)	The acute oral toxicity (LD ₅₀) of GR 572 Technical to the Mallard Duck.	45499001	Makhteshim-Agan of North America Inc.	OWN	
71-1 (OPPTS 850.2100)	"Rimon" technical - Acute oral toxicity (LD ₅₀) to the Bobwhite quail (<i>Colinus virginianus</i>).	45476801	Makhteshim-Agan of North America Inc.	OWN	
71-2 (OPPTS 850.2200)	The dietary toxicity (LC ₅₀) of GR 572 to the Bobwhite quail.	45499002	Makhteshim-Agan of North America Inc.	OWN	
71-2 (OPPTS 850.2200)	The dietary toxicity (LC ₅₀) of GR 572 to the Mallard Duck.	45499003	Makhteshim-Agan of North America Inc.	OWN	
71-4 (OPPTS 850.2300)	"Rimon" technical: Reproduction in Bobwhite quail.	45638218	Makhteshim-Agan of North America Inc.	OWN	
71-4 (OPPTS 850.2300)	"RIMON" Technical: Reproduction in Mallard duck.	45638219	Makhteshim-Agan of North America Inc.	OWN	
72-1 (OPPTS 850.1075)	The acute toxicity of GR 572 Technical to Rainbow trout (<i>Salmo gairdneri</i>).	45499004	Makhteshim-Agan of North America Inc.	OWN	
72-1 (OPPTS 850.1075)	The acute toxicity of GR 572 Technical to Bluegill sunfish (<i>Lepomis macrochirus</i>).	45499005	Makhteshim-Agan of North America Inc.	OWN	
72-1 (OPPTS 850.1075)	275-352 I: Acute toxicity to Rainbow trout	45499006	Makhteshim-Agan of North America Inc.	OWN	
72-2 (OPPTS 850.1010)	"Rimon" technical: Acute toxicity to the <i>Daphnia magna</i> .	45476802	Makhteshim-Agan of North America Inc.	OWN	
72-2 (OPPTS 850.1010)	275-352 I: Acute toxicity to <i>Daphnia magna</i> .	45499007	Makhteshim-Agan of North America Inc.	OWN	
72-3 (OPPTS 850.1075)	Novaluron: Acute Toxicity to Sheepshead Minnow (<i>Cyprinodon variegatus</i>) Under Flow-Through Conditions.	45638210	Makhteshim-Agan of North America Inc.	OWN	
72-3 (OPPTS 850.1025) (draft guideline)	Novaluron: Acute Toxicity to Eastern Oyster (<i>Crassostrea virginica</i>) Under Flow-Through Conditions.	45638208	Makhteshim-Agan of North America Inc.	OWN	
72-3 (OPPTS 850.1035)	Novaluron: Acute Toxicity to Mysids (<i>Americamysis bahia</i>) Under Flow-Through Conditions.	45638209	Makhteshim-Agan of North America Inc.	OWN	
72-4 (OPPTS 850.1300)	¹⁴ C-"RIMON": <i>Daphnia magna</i> Reproduction test	45638211	Makhteshim-Agan of North America Inc.	OWN	
72-4 (OPPTS 850.1300)	(Carbon 14)-"Rimon": <i>Daphnia magna</i> Reproduction Test: Final Report. Project Number: MAK/405, MAK405/974265	46581401	Makhteshim-Agan of North America Inc.	OWN	
72-4 (OPPTS 850.1350)	Novaluron: Life Cycle Toxicity Test with Mysids (<i>Americamysis bahia</i>).	45638212	Makhteshim-Agan of North America Inc.	OWN	40



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DATA MATRIX

Date: March 16, 2010			EPA Reg. No./File Symbol 11678-57	Page of 18	
Applicant's/Registrants Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609			Product: RIMON® Technical		
Ingredient Novaluron					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
72-4 (OPPTS 850.1400)	¹⁴ C-"RIMON" Technical: Fish early life stage toxicity test for Fathead minnow (<i>Pimephales promelas</i>).	45638213	Makhteshim-Agan of North America Inc.	OWN	
72-5 (OPPTS 850.1500)	Novaluron: Determination of effects on the reproduction of fathead minnow (<i>Pimephales promelas</i>).	45638214	Makhteshim-Agan of North America Inc.	OWN	
OPPTS 860.1135	(Carbon 14) "Rimon" to Assess the Toxicity to the Sediment Dwelling Phase of the Midge Chironomus riparius. Project Number: MAK/508, MAK/508/992185, R/10339.	46581402	Makhteshim-Agan of North America Inc.	OWN	
72-6 (OPPTS 850.1730)	¹⁴ C-"RIMON": Bioconcentration in Bluegill sunfish	45638215	Makhteshim-Agan of North America Inc.	OWN	
72-7 (OPPTS 850.1950)	Simulated or actual field testing – aquatic organisms	NA	NA	NA	Not required.

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: March 16, 2010			EPA Reg. No./File Symbol 11678-57	Page of 18	
Applicant's/Registrants Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609			Product: RIMON® Technical		
Ingredient Novaluron					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Ecological Effects (Plant Protection):					
121-1 (OPPTS 850.4025)	Target Area phytotoxicity	NA	NA	NA	Not required
122-1 (OPPTS 850.4100)	Tier 1: Seed germination / seedling emergence	NA	NA	NA	Not required
122-1 (OPPTS 850.4150)	Tier 1: Vegetative vigor	NA	NA	NA	Not required
122-2 (OPPTS 850.4400)	Tier 1: Aquatic plant growth	NA	NA	NA	Not required
123-1 (OPPTS 850.4200)	Tier 2: Seed germination	NA	NA	NA	Not required
123-1 (OPPTS 850.4225)	Tier 2: Seedling emergence	NA	NA	NA	Not required
123-1 (OPPTS 850.4250)	Tier 2: Vegetative Vigor	NA	NA	NA	Not required
123-2 (OPPTS 850.5400)	"RIMON": Higher plant (<i>Lemna</i>) growth inhibition test	45638223	Makhteshim-Agan of North America Inc.	OWN	
123-2 (OPPTS 850.5400)	"RIMON" Technical: Algal growth inhibition assay	45638221	Makhteshim-Agan of North America Inc.	OWN	
123-2 (OPPTS 850.5400)	275-352 I: Algal growth inhibition assay. 45638221	45638222	Makhteshim-Agan of North America Inc.	OWN	
124-1 (OPPTS 850.4300)	Tier 3: Terrestrial field	NA	NA	NA	Not required
124-2 (OPPTS 850.4450)	Tier 3: Terrestrial – aquatic field	NA	NA	NA	Not required
					42



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

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DATA MATRIX

Date: March 16, 2010			EPA Reg. No./File Symbol 11678-57	Page of 18	
Applicant's/Registrants Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609			Product: RIMON® Technical		
Ingredient Novaluron					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<u>Ecological Effects (Nontarget insects):</u>					
141-1 (OPPTS 850.3020)	Rimon (Novaluron) Technical: Acute toxicity to honey bees (<i>Apis mellifera</i>)...	45638220	Makhteshim-Agan of North America Inc.	OWN	
141-2 (OPPTS 85D.3030)	Honeybee – toxicity of residues on foliage	NA	NA	NA	Not required
141-4	Honeybee – subacute feeding study	NA	NA	NA	Not required
141-5 (OPPTS 850.3040)	Field testing for pollinators	NA	NA	NA	Not required
142-1	Acute toxicity to aquatic insects	NA	NA	NA	Not required
142-1	Aquatic insect life-cycle study	NA	NA	NA	Not required
142-3	Simulated or actual field testing for aquatic insects	NA	NA	NA	Not required
143-1 thru 143-3	Nontarget insect testing – predators and parasites	NA	NA	NA	Not required

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: March 16, 2010

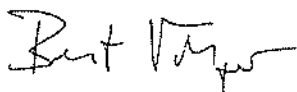
EPA Reg. No./File Symbol 11678-57

Page 18 of 18

Applicant's/Registrants Name & Address: Makhteshim-Agan of North America Inc.
 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609

Product: RIMON® Technical

Ingredient Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<u>Other Studies:</u>					
NONE	"RIMON" Technical: Prolonged toxicity to Rainbow trout under flow-through conditions. 28 Day study.	45638216	Makhteshim-Agan of North America Inc.	OWN	
NONE	"Rimon" Technical: Acute toxicity (LC ₅₀) to the earthworm (<i>Eisenia foetida</i>).	45638224	Makhteshim-Agan of North America Inc.	OWN	
NONE	Chlorophenyl urea: Acute toxicity (LC ₅₀) to the earthworm (<i>Eisenia foetida</i>).	45638225	Makhteshim-Agan of North America Inc.	OWN	
NONE	Rimon Technical: Effects on soil non-target micro-organisms.	45638217	Makhteshim-Agan of North America Inc.	OWN	
NONE	Probabilistic Modeling of Novaluron Exposure to Aquatic Non-target Organisms and Drinking Water Associated with Use on Cotton and Apples.	45638402	Makhteshim-Agan of North America Inc.	OWN	
	Signature: 		Name and Title: Bert Volger, Ph.D., Consultant for Makhteshim-Agan of North America, Inc.		Date: 03/16/2010

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Material Sent for Data Extraction

Reg. # 11678-57

Description: New Tech Label Adding Sweet Corn

☐ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 9-30-2011

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☐ Other: _____

☐ Decision #: D-43248D

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Jennifer Ghines

Phone: 305-59107 Division: RD

Date: 9-15-2012

May 25, 2010

John,

These are section 3 label amendments (EPA Reg # 66222-35, D432482 and 11678-57, D432480 (technical) submitted with an IR-4 petition (PP# 0E7723) for use of novaluron on sweet corn. The Minor Use Team (MUT) will send data into review for this petition to HED for the human health risk assessments and EFED for the drinking water estimates.

EFED requests that the Product Management Team send the section 3 label amendments into review as well in order for EFED to conduct the ecological risk assessment.

Please note this is a joint review project with PMRA so it is important this be sent into review right away. Though the PRIA date is in ~~June~~ ^{August} of 2011 the joint review schedule with PMRA will make the due date in mid February for the FR and late February for the label.

Laura Nollen on the MUT will be taking the lead for this action. At this time we were not going to schedule a team meeting but please let us know if you would like us to schedule one.

The MUT has created a docket for this action and have requested that you and Jennifer Gaines be given rights to the docket in order for the PM team to include the Notice Pesticide Products; Registration Applications in this docket. **The docket # is EPA-HQ-OPP-2010-0471.**

Please let me know if you need any additional information.

Thanks

Barbara Madden
305-6463

Meeting Minutes - Conference Call to Discuss Joint Review Novaluron on Sweet Corn
between PMRA and EPA
Monday, May 17, 2010

Participants: Susan Wong and Melissa Watchorn – PMRA
Barbara Madden, Laura Nollen, Dana Vogel - EPA

- Novaluron on sweet corn
 - PMRA took lead on review of for residue chemistry data.
 - Primary data review – exchange of DERs 09/13/10
 - Secondary data review – exchange 10/11/10
 - Human Health and Environmental Risk assessments complete 01/10/11
 - Expected regulatory decision date 02/15/11

PMRA:

Martine Moncion Administrative Coordinator martine.moncion@hc-sc.gc.ca

Melissa Watchorn HED Evaluator (Food Residues) melissa.watchorn@hc-sc.gc.ca

EPA:

Laura Nollen Administrative Coordinator Nollen.Laura@epamail.epa.gov

Julie VanAlstine HED Evaluator VanAlstine.Julie@epa.gov

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 4-22-10

Experts In-Processing Signature: MF Harrington Date 4-28-10 Fee Paid: Yes

Division management contacted on issues No Yes Date

EPA Reg. Number: <u>11678-57</u>		EPA Receipt Date: <u>4-22-10</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form) a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)			yes	no	X
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)			yes	no	
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack) a) Selective Method (Fee category experts use) b) Cite-All (Fee category experts use) c) Applicant owns all data (Fee category experts use)			yes	no	
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

KE 0 Study associated w/ Jacket (480735) has passed 86-5 review.

PSS

MRID 480735

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses even if a product is **currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/oppr001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/oppr001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

*File
com*

May 26, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-432480
EPA File Symbol or Registration Number: 11678-57
Product Name: RIMON TECHNICAL
EPA Receipt Date: 22-Apr-2010
EPA Company Number: 11678
Company Name: MAKHTESHIM CHEMICAL WORKS LTD

EPHI GUR
MAKHTESHIM-AGAN OF NORTH AMERICA, INC.
MAKHTESHIM CHEMICAL WORKS LTD
4515 FALLS OF NEUSE RD, SUITE 300
RALEIGH, NC 27609-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action previously identified as R180 has been reclassified as Action Code: R170

NEW USE; EACH ADDITIONAL NEW FOOD USE;


No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-6249.

Sincerely,


Front End Processing Staff
Information Technology & Resources Management Division



Re: Fw: Action was coded incorrectly - could we get it changed in OPPIN? 

Linda Arrington to: John Jamula

05/26/2010 01:44 PM

Cc: Barbara Madden

History: This message has been replied to.

Hi Everyone,

If no reduce risk documentation then the code should be changed to R170. Barbara if you can provide the Decision number for the action, JJ will change it.

Thanks

Linda Arrington
Registration Division
703 305 6249
703 305 6920 (fax)

John Jamula

This is Linda's call ... JJ>

05/26/2010 01:14:05 PM

From: John Jamula/DC/USEPA/US
To: Barbara Madden/DC/USEPA/US@EPA
Cc: Linda Arrington/DC/USEPA/US@EPA
Date: 05/26/2010 01:14 PM
Subject: Re: Fw: Action was coded incorrectly - could we get it changed in OPPIN?

This is Linda's call ... JJ>

Barbara Madden

Just wanted to check with the two of you on whet...

05/26/2010 01:02:56 PM

From: Barbara Madden/DC/USEPA/US
To: John Jamula/DC/USEPA/US@EPA, Linda Arrington/DC/USEPA/US@EPA
Date: 05/26/2010 01:02 PM
Subject: Fw: Action was coded incorrectly - could we get it changed in OPPIN?

Just wanted to check with the two of you on whether this should be recoded or not? I would appreciate it if you could let me know so when can put this action into review. Thanks Barbara
----- Forwarded by Barbara Madden/DC/USEPA/US on 05/26/2010 01:01 PM -----

From: Barbara Madden/DC/USEPA/US
To: John Jamula/DC/USEPA/US@EPA, Linda Arrington/DC/USEPA/US@EPA
Cc: John Hebert/DC/USEPA/US@EPA, Laura Nollen <Nollen.Laura@epamail.epa.gov>, Stephen Schaible/DC/USEPA/US@EPA
Date: 05/20/2010 04:25 PM
Subject: Action was coded incorrectly - could we get it changed in OPPIN?

Linda and JJ,

I am inprocessing an IR-4 petition for use of novaluron on sweet corn. This action was inprocessed and coded as a R-180 (reduced risk) however I do not see that IR-4 requested risk status for this chemical in their cover letter nor submitted any documentation to support reduced risk classification. I do see where the registrant mentions it in the form for the section 3 application but there is no other documentation. I thought that they had to submit the documentation at the time of submission to get the shorter timeline? If so I would like these actions to be coded as a R-170 so that the correct PRIA date shows up in OPPIN.

0E7723 - D432483



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 26, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-432480
EPA File Symbol or Registration Number: I1678-57
Product Name: RIMON TECHNICAL
EPA Receipt Date: 22-Apr-2010
EPA Company Number: 11678
Company Name: MAKHTESHIM CHEMICAL WORKS LTD

EPHI GUR
MAKHTESIM-AGAN OF NORTH AMERICA, INC.
MAKHTESHIM CHEMICAL WORKS LTD
4515 FALLS OF NEUSE RD, SUITE 300
RALEIGH, NC 27609-

SUBJECT: Receipt of Amendment and IR-4 Fee Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application for amendment and IR-4 fee waiver request. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R180

NEW USE;REDUCED RISK;EACH ADDITIONAL NEW FOOD USE;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If the determination indicates that payment is due, you will receive instructions for submitting payment at that time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 305-6249.

Sincerely,

A handwritten signature in cursive script, reading "Teresa Downs", is positioned below the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{8731192~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: IR-4

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr.

5

Receipt No.

S-

873119

EPA File Symbol/Reg. No.

11678-57

Pin-Punch Date:

4/22/2010

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R180

Granted: R180

Amount Due: \$ 57,120

Parent/Child Decisions:

Petition # OE 7723

06222-35

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: A. Hill

Date: 4/26/10

Remarks:

Receipt for Section 3

S: 873119

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 11678 MAKHTESHIM CHEMICAL WORKS LTD

V

Risk Manager: Registration Division, Risk Management Team 7

Product #: 11678-57

Product Name: RIMON TECHNICAL

Override:

Me Too

Me Too

Section3:

Product Name:

Application Date: 12-Apr-2010

id

OPP Rec'd Date: 22-Apr-2010

id

Front End Date: 22-Apr-2010

id

Risk Manager Send Date:

id

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Petition of tolerances and adding a new food use, sweet corn

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information


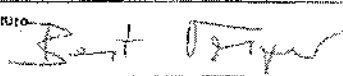
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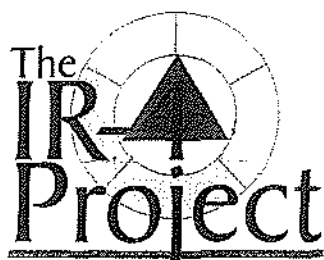
Receipt Content

Des

Paper Label

View/Edit

		United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I					
1. Company/Product Number 11678-57		2. EPA Product Manager Barbara Madden		3. Proposed Classification <input checked="" type="checkbox"/> New <input type="checkbox"/> Restricted	
4. Company/Product (Name) RIMON TECHNICAL		PM# IR-4 Projects			
5. Name and Address of Applicant (Include ZIP Code) Makhteshim Chemical Works c/o Makhteshim Agan of North America, Inc. 4515 Falls of Neuse Rd, Suite 300 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____			
Section - II					
<input checked="" type="checkbox"/> Amendment - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____			
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input type="checkbox"/> "No Too" Application.			
<input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Other - Explain below.			
Explanation: Use additional pages if necessary. (For section I and Section II.) Position of tolerances and adding a new food use (sweet corn). Submission of data (IR-4) to support this application (Reduced Risk). FEE CATEGORY: R180 - additional food use; reduced risk; 10 month review process FEE DUE: \$ 57,120; waived by IR-4 EMAIL: bertvolger@comcast.net					
Section - III					
1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. _____ No. per container _____	If "Yes" Package wgt. _____ No. per container _____		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size of Retail Container _____		5. Location of Label Directions <input type="checkbox"/> _____	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			
Section - IV					
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Bert Volger		Title Consultant for MANA		Telephone No. (include Area Code) 610-793-3222	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Consultant for MANA			
4. Typed Name Bert Volger		5. Date 04/12/2010			



Providing Safe and Effective Pest
Management Solutions for
Specialty Crop Growers

480735-00
IR-4 Headquarters
Rutgers, The State University of New Jersey
500 College Road East, Suite 201 W
Princeton, NJ 08540
732.932.9575
fax: 609.514.2612
ir4.rutgers.edu

April 20, 2010

Ms. Barbara Madden
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Dear Ms. Madden:

Re: Novaluron

Rimon 0.83 EC Insecticide

EPA Reg. No.: 66222-35

Novaluron, 1-[3-chloro-4-[1,1,2-trifluoro-2-trifluoro-methoxyethoxy]phenyl]-3-(2,6-difluorobenzoyl)urea

New Uses:

- 1) Corn (sweet): 1 analytical IR-4 Report, PR 9838/sweet corn with 14 field trials

Category: R170

ELECTRONIC SUBMISSION TO FOLLOW

The undersigned, Raymond C. Leonard, Associate Coordinator, Interregional Research Project No. 4, State Agricultural Experiment Station, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, New Jersey 08540 on behalf of the IR-4 Project and the Agricultural Experiment Stations of Idaho, submit this petition pursuant to Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the pesticide chemical, novaluron (40 CFR180.598).

List of Studies Submitted in Support of Proposed Tolerances for Novaluron:

Vol. No	Volume Title	MRID No. / PP No.
1	Petition (Administrative Volume only)	
2	Novaluron: Magnitude of the Residue on Corn (Sweet)	48073501

As per the "IR-4 Waiver Determination under the Pesticide Registration Improvement Act" signed by OPP Director James J. Jones, the IR-4 tolerance petition for novaluron on corn (sweet) is in the public interest. Therefore, IR-4 in cooperation with the registrant, is requesting a waiver of the registration services fee for this petition.

The hard copy (2 copies of each volume) submission is enclosed with this transmission.

*Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES,
in cooperation with the State Agricultural Experiment Stations, and USDA-ARS.*

RUTGERS
THE STATE UNIVERSITY
OF NEW JERSEY

IR-4 Project, Novaluron Submission, April 20, 2010

Also enclosed are the following:

- EPA Form 8570-1 (Rev. 3-94) for Rimon 0.83 EC Insecticide and the technical material
- EPA Form 8570-34 (Rev. 9-97) Certification With Respect to Citation of Data Statement for Rimon 0.83 EC Insecticide and the technical material
- EPA Form 8570-35 (Rev. 9-97) Data Matrix Internal Agency Use Copy and Data Matrix Publicly Releasable Copy for Rimon 0.83 EC Insecticide and the technical material
- Proposed Labels for the use of Rimon 0.83 EC Insecticide (5 copies of proposed labels), also included in Section B of the Petition (Administrative Volume).
- Label for novaluron technical (5 copies).
- Notice of Filing.
- A letter with the registrant's response to 40 CFR 158 immunotoxicity (OPPTS Guideline 870.7800) and acute and subchronic neurotoxicity (OPPTS Guideline 870.6200) data required for pesticide registration.

For all questions regarding the proposed label, please contact the registrant.

Yours very truly,

Interregional Research Project No. 4

Petitioner

Per Raymond C. Leonard

Raymond C. Leonard
Associate Coordinator
IR-4 Project Headquarters
Rutgers, The State University of New Jersey

Copies: Robert C. Everich (Makhteshim-Agan of North America, Inc.), Judy Ball (Chemtura), Shirley Archambault, IR-4 Regional Coordinators (Sec. B & F only), Requestors (Sec. B & F only), Diane Infante



**Makhteshim Agan of
North America, Inc.**

April 12, 2010

Document Processing Desk (IR-4)
Office of Pesticide Programs (H7505C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW.
Washington, DC 20460-0001

Attention: Ms. Barbara Madden,
Minor Use Office

Subject: NOVALURON (Chemical Code 124002)
RIMON® Technical: EPA Reg. No. 11678-57)
RIMON® 0.83 EC Insecticide (EPA Reg. No. 11678-57),
IR-4 Petition for Establishment of Tolerance for Novaluron Residues in or on Corn,
Sweet (Kernels plus Cob with Husk Removed, Forage, and Stover),
Data Requirements (OPPTS 870.7800, 870.6200)

Dear Ms. Madden:

Referring to the recently imposed data requirements (40 CFR 158 dated 12/26/2007) for immunotoxicity (OPPTS 870.7800), acute and subchronic neurotoxicity (OPPTS 870.6200), Makhteshim-Agan of North America, Inc. (MANA) hereby confirms that the neurotoxicity data requirements have been met (MRID 45082601, 46086204).

MANA is presently addressing the immunotoxicity data requirements as requested in the Agency's letter dated December, 30, 2009, and will submit the appropriate data according to OPPTS Guideline 870.7800 by the end of December 2011.

If you have any questions regarding this summary or the subject petition, please contact me under 212-896-4945 or Bert Volger at 610-793-3222.

Very truly yours,

for Robert C. Everich, Ph.D.
Senior Scientist
Makhteshim-Agan of North America Inc.

Cc: Ray Leonard (IR-4)

4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609
Tel: 919-256-9305 Fax: 919-256-9308



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Bert Volger
Makhteshim Agan of North America, Inc.
4515 Falls of Neuse Rd., Suite 300
Raleigh, NC 27609

SEP 30 2011

Dear Mr. Volger:

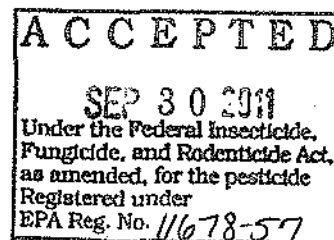
Subject: Label Amendment to Rimon Technical Adding Sweet Corn
EPA Registration No. 11678-57
Submission Date: April 12, 2010
OPP Decision Number: D-432480

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records. Please submit one (1) final printed copy for the above mentioned label before releasing the product for shipment. If you have any questions regarding this label, please contact Jennifer Gaines at (703) 305-5967.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John Hebert", written over a large, stylized circular flourish.

John Hebert
Product Manager (07)
Insecticide-Rodenticide Branch
Registration Division (7505P)



TECHNICAL

(Novaluron)

For The Manufacture of Insecticides Only

ACTIVE INGREDIENT: Novaluron:	% BY WT.
1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]-	
3-(2,6-difluorobenzoyl)urea.....	98.5%
OTHER INGREDIENTS:	1.5%
	TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact PROSAR at 1-877-250-9291 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters except in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

NET CONTENTS 55 POUNDS



EPA Reg. No. 11678-57
EPA Est. No. [REDACTED]

Page 1 of 3

Manufactured for:
Makhteshim Chemical Works, Ltd.
c/o Makhteshim-Agan of North America, Inc.
4515 Falls of Neuse Rd., Suite 300
Raleigh, NC 27609
919-256-9305

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This pesticide is for the further manufacture of formulated insecticides only. Formulators using this product are responsible for obtaining EPA registration for their formulated products.

Only for formulation into an insecticide for the following uses:

(1) Beans (snap, dry); Berries (low-growing), including cranberry, lingonberry, muntries, partridgeberry, bearberry, bilberry, lowbush blueberry, cloudberry; Bushberries, including: blueberry (highbush and lowbush), currant, elderberry, gooseberry, and huckleberry; Cotton; Cucurbit vegetables, including balsam apple, balsam pear, chayote (fruit) cantaloupe, cucumber, chinese cucumber, gherkin (west indian), edible gourd, melon, citron melon, muskmelon, bittermelon, pumpkin, squash, summer squash, winter squash, watermelon and chinese waxgourd; Fruiting vegetables (field grown), including tomatoes (including bush, currant and tree tomatoes), peppers, eggplants (including african, pea and scarlet eggplants), tomatillo, groundcherry, pepino, okra, cocona, goji berry, garden huckleberry, martynia, naranjilla, roselle, and sunberry; Head and stem brassica vegetables including: broccoli, chinese broccoli, brussel sprouts, cabbage, cavalo broccolo, cauliflower, chinese broccoli (gai lon), chinese cabbage (napa), chinese mustard (gai choy), and kohlrabi; Leafy brassica greens, including: broccoli raab, chinese cabbage (bok choy), collards, kale, mizuna, mustard greens, mustard spinach, and rape greens; Ornamentals (container grown ornamentals in green-houses, shade-houses, and outdoor nurseries); Pome fruit; Potatoes/ sweet potatoes; Stone fruits, including apricots, cherries (sweet and tart), nectarines, peaches, plums and prune plums; strawberry; sugarcane; sweet corn; Swiss chard; Turnip greens.

(2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and

(3) Uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

CONTAINER HANDLING:

Liner: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities.

Drum: Refillable container. Refill this container with novaluron only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. If drum is contaminated and can not be reused, dispose of in a sanitary landfill or by incineration if allowed by State and local authorities.

LIMITATION OF WARRANTY AND LIABILITY

Read the entire directions for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES and LIMITATIONS OF LIABILITY.**

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Makhteshim Chemical Works, Ltd. All such risks shall be assumed by the user or buyer.


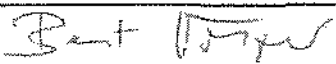
DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Makhteshim Chemical Works, Ltd. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Makhteshim Agan of North America, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Makhteshim Chemical Works, Ltd. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Makhteshim Chemical Works, Ltd.'s election, the replacement of product.

Copyright 2002

RIMON® is a registered trademark of Makhteshim Chemical Works Ltd.

Rimon Technical (11678-57); (EPA approved 02-12-2010 w comments incorporated)
Add sweet corn 04-12-2010

 <p align="center">UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460</p>		
<p>Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2-137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.</p>		
<p align="center">Certification with Respect to Citation of Data</p>		
Applicant's/Registrant's Name, Address, and Telephone Number Makhteshim-Agan North America Inc., 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609		EPA Registration Number/File Symbol 1 167B-57
Active ingredient(s) and/or representative test compound(s) Hovaluron		Date April 12, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Insecticide for use on ornamentals, bushes, berries, cotton, leafy classics greens, peaches, pome fruits		Product Name RIMON TECHNICAL
<p>NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 6570-27).</p>		
<input type="checkbox"/> I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).		
<p align="center">SECTION I: METHOD OF DATA SUPPORT (Check one method only)</p>		
<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).		<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
<p align="center">SECTION II: GENERAL OFFER TO PAY</p>		
<p>(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)</p> <input type="checkbox"/> I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.		
<p align="center">SECTION III: CERTIFICATION</p>		
<p>I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.</p>		
<p>I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.</p>		
<p>I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA, and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.</p>		
<p>I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.</p>		
<p>I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.</p>		
Signature 	Date 04/12/2010	Typed or Printed Name and Title Bert Volger Ph.D., Consultant to MANA

EPA Form 8570-30 (9-97) Electronic and Paper versions available. Submit only Paper version.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

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DATA MATRIX

Date: April 12, 2010	EPA Reg. No./File Symbol: 11678-57	Page of 18
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609	Product: RIMON® Technical	

Ingredient: Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Physical and Chemical Properties:					
158.155 (OPPTS 830.1550)	"Rimon" (Novaluron) Product Chemistry Data: Product Identity and Disclosure of Ingredients, Description of Beginning Material and Manufacturing, and Discussion of Formation of Impurities.	44961003	Makhteshim-Agan of North America Inc.	OWN	
158.160 (OPPTS 830.1600)	"Rimon" (Novaluron) Product Chemistry Data: Product Identity and Disclosure of Ingredients, Description of Beginning Material and Manufacturing, and Discussion of Formation of Impurities.	44961003	Makhteshim-Agan of North America Inc.	OWN	
158.162 (OPPTS 830.1620)	"Rimon" (Novaluron) Product Chemistry Data: Product Identity and Disclosure of Ingredients, Description of Beginning Material and Manufacturing, and Discussion of Formation of Impurities.	44961003	Makhteshim-Agan of North America Inc.	OWN	
158.165 (OPPTS 830.1650)	"Rimon" (Novaluron) Product Chemistry Data: Product Identity and Disclosure of Ingredients, Description of Beginning Material and Manufacturing, and Discussion of Formation of Impurities.	44961003	Makhteshim-Agan of North America Inc.	OWN	
158.167 (OPPTS 830.1670)	"Rimon" (Novaluron) Product Chemistry Data: Product Identity and Disclosure of Ingredients, Description of Beginning Material and Manufacturing, and Discussion of Formation of Impurities.	44961003	Makhteshim-Agan of North America Inc.	OWN	
158.170 (OPPTS 830.1700)	Rimon-Quantification of Active Ingredient and Impurities present at or above 0.1% in technical Rimon (FIFRA Guideline-Series 62)	44961004	Makhteshim-Agan of North America Inc.	OWN	
158.175 (OPPTS 830.1750)	Rimon-Quantification of Active Ingredient and Impurities present at or above 0.1% in technical Rimon (FIFRA Guideline-Series 62)	44961004	Makhteshim-Agan of North America Inc.	OWN	
158.180 (OPPTS 830.1800)	Rimon-Quantification of Active Ingredient and Impurities present at or above 0.1% in technical Rimon (FIFRA Guideline-Series 62)	44961004	Makhteshim-Agan of North America Inc.	OWN	
64-1 (OPPTS 830.1900)	Submittal of samples	NA	Makhteshim-Agan of North America Inc.	OWN	
63-2 (OPPTS 830.6302)	Rimon Technical: Determination of the physico-chemical properties. GLP, Unpublished	44961007	Makhteshim-Agan of North America Inc.	OWN	
63-2 (OPPTS 830.6302)	Rimon (Pure): Determination of the physico-chemical properties.	44961006	Makhteshim-Agan of North America Inc.	OWN	
63-3 (OPPTS 830.6303)	Rimon Technical: Physical State; Stability; pH; and solubility.	44961005	Makhteshim-Agan of North America Inc.	OWN	
63-4 (OPPTS 830.6304)	Rimon Technical: Determination of the physico-chemical properties. GLP, Unpublished	44961007	Makhteshim-Agan of North America Inc.	OWN	
63-4 (OPPTS 830.6304)	Rimon (Pure): Determination of the physico-chemical properties.	44961006	Makhteshim-Agan of North America Inc.	OWN	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: April 12, 2010

EPA Reg. No./File Symbol: 11678-57

Page of 18

Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc.
 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609

Product: RIMON® Technical

Ingredient: Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-5 (OPPTS 830.7200)	Rimon (Pure): Determination of the physico-chemical properties.	44961006	Makhteshim-Agan of North America Inc.	OWN	
63-6 (OPPTS 830.7220)	Boiling point/boiling range	NA	NA	NA	Not required
63-7 (OPPTS 830.7300)	Rimon (Pure): Determination of the physico-chemical properties.	44961006	Makhteshim-Agan of North America Inc.	OWN	
63-8 (OPPTS 830.7840)	Rimon Technical: Determination of the physico-chemical properties. GLP, Unpublished	44961007	Makhteshim-Agan of North America Inc.	OWN	
63-8 (OPPTS 830.7840)	275-352 I: Water solubility	Not assigned	Makhteshim-Agan of North America Inc.	OWN	
63-8 (OPPTS 830.7860)	Rimon Technical: Determination of the physico-chemical properties. GLP, Unpublished	44961007	Makhteshim-Agan of North America Inc.	OWN	
63-8 (OPPTS 830.7860)	275-352 I: Water solubility	45651501	Makhteshim-Agan of North America Inc.	OWN	
63-9 (OPPTS 830.7950)	Rimon (Pure): Determination of the physico-chemical properties.	44961006	Makhteshim-Agan of North America Inc.	OWN	
63-10 (OPPTS 830.7370)	Rimon Technical: Color, Odor, UV/Vis Absorption, Melting point, Density, Dissociation Constant, Partition Coefficient (Octanol / water), Solubility, and Vapor Pressure.	44961006	Makhteshim-Agan of North America Inc.	OWN	
63-11 (OPPTS 830.7550)	Rimon (Pure): Determination of the physico-chemical properties.	44961006	Makhteshim-Agan of North America Inc.	OWN	
63-12 (OPPTS 830.7000)	Rimon Technical: Physical State; Stability; pH; and solubility.	44961005	Makhteshim-Agan of North America Inc.	OWN	
63-13 (OPPTS 830.6313)	Rimon Technical: Physical State; Stability; pH; and solubility.	44961005	Makhteshim-Agan of North America Inc.	OWN	
63-14 (OPPTS 830.6314)	Oxidation/reduction: chemical incompatibility	NA	NA	NA	Not required
63-15 (OPPTS 830.6315)	Rimon Technical: Determination of the physico-chemical properties. GLP, Unpublished	44961007	Makhteshim-Agan of North America Inc.	OWN	
63-16 (OPPTS 830.6316)	Rimon Technical: Determination of the physico-chemical properties. GLP, Unpublished	44961007	Makhteshim-Agan of North America Inc.	OWN	
63-17 (OPPTS 830.6317)	Comb. A. (2003) "Rimon" (Technical Grade) Storage Stability. Project	46086201	Makhteshim-Agan of North America Inc.	OWN	

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DATA MATRIX

Date: April 12, 2010

EPA Reg. No./File Symbol: 11678-57

Page of 18

Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc.
 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609

Product: RIMON® Technical

Ingredient: Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Number: MAK760, R/14502, MAK760/032350.				
63-18 (OPPTS 830.6318)	Viscosity	NA	NA	NA	Not required
63-19 (OPPTS 830.7100)	Miscibility	NA	NA	NA	Not required
63-20 (OPPTS 830.6320)	Corrosion Characteristics	NA	NA	NA	Not required
63-21 (OPPTS 830.6321)	Dielectric breakdown voltage	NA	NA	NA	Not required
NONE (OPPTS 830.7050)	Rimon (Pure): Determination of the physico-chemical properties.	44961006	Makhteshim-Agan of North America Inc.	OWN	



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DATA MATRIX

Date: April 12, 2010		EPA Reg. No./File Symbol: 11678-57		Page of 18	
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609		Product: RIMON® Technical			
Ingredient: Novaluron					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Residue Chemistry:					
171-2 (OPPTS 860.1100)	"Rimon" (Novaluron) Product Chemistry Data: Product Identity and Disclosure of Ingredients, Description of Beginning Material and Manufacturing, and Discussion of Formation of Impurities.	44961003	Makhteshim-Agan of North America Inc.	OWN	
171-3 (OPPTS 860.1200)	Directions for use	NA	Makhteshim-Agan of North America Inc.	OWN	See attached Product Label
171-4 (OPPTS 860.1300)	¹⁴ C "RIMON": Metabolism in apples.	45638226	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1300)	¹⁴ C "RIMON": Metabolism in cabbages.	45638227	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1300)	¹⁴ C "RIMON": Metabolism in potatoes.	45771803	Makhteshim-Agan of North America Inc.	OWN	

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DATA MATRIX

Date: April 12, 2010	EPA Reg. No./File Symbol: 11678-57	Page of 18
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609	Product: RIMON® Technical	

Ingredient: Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
171-4 (OPPTS 860.1300)	¹⁴ C-"RIMON": Metabolism in cotton.	45638302	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1300)	¹⁴ C "RIMON" Metabolism in the lactating goat.	45638303	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1340)	Development and validation of an analytical method for the determination of Rimon in apples, cabbages and potatoes	45638304	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1340)	Radiovalidation of Residue Method for the Determination of Novaluron in Cotton. Project Number: 1122W/f, f122W, 2002/020.	46714901	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1340)	Independent Validation of the Analytical Method for Novaluron (Rimon) in Apples.	45638305	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1340)	Independent Validation (ILV) of an HPLC/UV Based Analytical Method for the Determination Novaluron in Cotton.	45638306	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1340)	The development and validation of methodology for the determination of RIMON residues in Bovine tissues (fat, kidney, liver, muscle), milk and eggs	45638307	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1340)	Radiovalidation of Analytical Method for Determination of Novaluron in Bovine Tissues. Project Number: MAK/797, MAK/797/032011, 2002/119.	46714902	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1340)	Determination of Novaluron in Sorghum Agricultural and Processing Commodities by LC-MS/MS. Project Number: 189, MANA/07102008. Unpublished study prepared by Morse Laboratories, Inc. 45 p.	47486302	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1340)	Novaluron: Independent laboratory validation (ILV) of methodology for the post-registration monitoring of residues of Novaluron in milk, muscle and liver.	45638308	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1340)	Novaluron: Laboratory validation of Methods for the analysis of novaluron in/on butter, processed meat, milk, white bread, lettuce, and dinner plate. Project No. 234C-106. Unpublished study prepared by Wildlife International.	48034901	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1380)	Storage stability: Magnitude of the Residue of Novaluron in Pome Fruit Raw Agricultural and Processed Commodities and Magnitude of the Residue of Novaluron in Cotton Raw Agricultural and Processed Commodities	45638420	Makhteshim-Agan of North America Inc.	OWN	Magnitude of the residue studies included storage stability testing.

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DATA MATRIX

Date: April 12, 2010	EPA Reg. No./File Symbol: 11678-57	Page of 18
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609		Product: RIMON® Technical

Ingredient: Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
171-4 (OPPTS 860.1380)	Storage stability: Evaluation of the freezer Storage stability of novaluron in/on butter, processed meat, milk, white bread, lettuce and dinner plate. Project No. 234C-107. Unpublished study prepared by Wildlife International.	48034902	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1400)	Development and validation of an analytical method for the determination of Rimon in groundwater.	45638309	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1400)	Novaluron: Development and validation of methodology for the determination of residues of Novaluron and its chlorophenyl urea metabolite (275-352 I) in drinking water, ground water and surface water.	45638310	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1400)	Residues in fish	NA	NA	NA	Not required
171-4 (OPPTS 860.1400)	Residues in irrigated crops	NA	NA	NA	Not required
171-4 (OPPTS 860.1460)	Residue in Food Commodities following application of a liquid formulation of novaluron as a space spray treatment in a simulated food handling. Report #14521A008. Unpublished study prepared by Landis International.	48034903	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1480)	"RIMON" Technical: Residues in milk and tissues of dairy cows	45638311	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1480)	"RIMON" Technical: Residue transfer study - accumulation and depletion of residues in eggs and tissues of laying hens. Project No. MAK/0900/062531, Makhteshim Chemical Works Ltd., Report No R-18701. plus supplemental information	46870601, 47486301	Makhteshim-Agan of North America Inc.	OWN	
171-13 (OPPTS 860.1650)	Submission of analytical reference standards	NA	NA	NA	Previously submitted (2001)
165-1 (OPPTS 860.1850)	14C-"RIMON": Accumulation in confined rotational crops. Huntingdon Life Sciences Ltd., UK, Report No. MAK559/002865. Makhteshim Chemical Works Ltd., Report No. R-11236	45638312	Makhteshim-Agan of North America Inc.	OWN	
165-2 (OPPTS 860.1900)	Rotational Crop Study: Novaluron treated mustard greens rotated with turnips and wheat	47180502	Makhteshim-Agan of North America Inc.	OWN	



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DATA MATRIX

Date: April 12, 2010	EPA Reg. No./File Symbol 11678-57	Page of 18
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609	Product: RIMON® Technical	

Ingredient Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Environmental Fate:					
161-1 (OPPTS 835.2120)	¹⁴ C "RIMON": Hydrolysis under laboratory conditions	44961008	Makhteshim-Agan of North America Inc.	OWN	
161-2 (OPPTS 835.2240)	¹⁴ C "RIMON": Photolytic degradation in water	45638203	Makhteshim-Agan of North America Inc.	OWN	
161-3 (OPPTS 835.2410)	¹⁴ C "RIMON": Photodegradation on soil...	45638204	Makhteshim-Agan of North America Inc.	OWN	
161-4 (OPPTS 835.2370)	Rimon (Pure): Determination of the physico-chemical properties	44961006	Makhteshim-Agan of North America Inc.	OWN	
162-1 (OPPTS 835.4100)	¹⁴ C - "RIMON": Aerobic Soil Metabolism (Pilot study).	44961010	Makhteshim-Agan of North America Inc.	OWN	
162-1 (OPPTS 835.4100)	¹⁴ C-"RIMON": Aerobic soil metabolism (Route of Degradation)	44961009	Makhteshim-Agan of North America Inc.	OWN	
162-1 (OPPTS 835.4100)	¹⁴ C-"RIMON": Aerobic soil rate of degradation	44961009	Makhteshim-Agan of North America Inc.	OWN	
162-2 (OPPTS 835.4200)	¹⁴ C-"RIMON": Anaerobic soil metabolism	45638205	Makhteshim-Agan of North America Inc.	OWN	
162-3 (OPPTS 835.4400)	Anaerobic Aquatic Metabolism of ¹⁴ C "RIMON"	45638207	Makhteshim-Agan of North America Inc.	OWN	
162-4 (OPPTS 835.4300)	¹⁴ C-"Rimon": Degradability and fate in the water/sediment system	45638206	Makhteshim-Agan of North America Inc.	OWN	
163-1 (OPPTS 835.1230)	¹⁴ C "RIMON": Adsorption/desorption on soil	44961012	Makhteshim-Agan of North America Inc.	OWN	
163-1 (OPPTS 835.1230)	¹⁴ C-275-352 I: Adsorption/desorption on soil	45638201	Makhteshim-Agan of North America Inc.	OWN	
163-1 (OPPTS 835.1240)	¹⁴ C- "RIMON": Soil column leaching	44961011	Makhteshim-Agan of North America Inc.	OWN	
					74



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DATA MATRIX

Date: April 12, 2010	EPA Reg. No./File Symbol 11678-57	Page of 18
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609	Product: RIMON® Technical	

Ingredient Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
163-2	Volatility (Lab)	NA	NA	NA	Not required
163-3	Volatility (Field)	NA	NA	NA	Not required
164-1 (OPPTS 835.6100)	Terrestrial Field Soil Dissipation of Novaluron. American Agricultural Services, Inc. Cary, N.C	45789204	Makhteshim-Agan of North America Inc.	OWN	
164-2 (OPPTS 835.6200)	Dissipation -- Aquatic sediment (field)	NA	NA	NA	Not required
164-3 (OPPTS 835.6300)	Dissipation -- Forestry (field)	NA	NA	NA	Not required
164-4 (OPPTS 835.6400)	Dissipation -- Combination and tank mixes (field)	NA	NA	NA	Not required
164-5 (OPPTS 835.6500)	Dissipation -- Soil, long-term	NA	NA	NA	Not required
165-1 (OPPTS 860.1850)	¹⁴ C-"RIMON": Accumulation in confined rotational crops.	45638312	Makhteshim-Agan of North America Inc.	OWN	
165-2 (OPPTS 860.1900)	Accumulation --crops	NA		NA	Not required
165-3	Accumulation studies -- irrigated crops	NA	NA	NA	Not required
165-4 (OPPTS 850.1730)	¹⁴ C-"RIMON": Bioconcentration in Bluegill sunfish	45638215	Makhteshim-Agan of North America Inc.	OWN	



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DATA MATRIX

Date: April 12, 2010	EPA Reg. No./File Symbol 1 t678-57	Page of 18
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609	Product: RIMON® Technical	

Ingredient Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Health Effects:					
81-1 (OPPTS 870.1100)	GR 572: Acute oral toxicity (LD ₅₀) in rats Inveresk.	44961001	Makhteshim-Agan of North America Inc.	OWN	
81-2 (OPPTS 870.1200)	Acute dermal toxicity to rats of GR 572 Tech	45003201	Makhteshim-Agan of North America Inc.	OWN	
81-3 (OPPTS 870.1300)	GR 572 Tech: Acute inhalation toxicity study in rats (Limit test)	45003202	Makhteshim-Agan of North America Inc.	OWN	
81-4 (OPPTS 870.2400)	Irritant effects on the rabbit eye of GR 572 Tech	45003203	Makhteshim-Agan of North America Inc.	OWN	
81-5 (OPPTS 870.2500)	Irritant effects on rabbit skin of GR 572 Tech	45003204	Makhteshim-Agan of North America Inc.	OWN	
81-6 (OPPTS 870.2600)	Skin sensitization test in Guinea Pigs of the test article GR 572 tech	44961002	Makhteshim-Agan of North America Inc.	OWN	
81-6 (OPPTS 870.2600)	RIMON® Technical - Skin sensitisation in the guinea-pig (incorporating a positive control using hexyl cinnamic aldehyde)	45084001	Makhteshim-Agan of North America Inc.	OWN	
81-7 (OPPTS 870.6100)	Acute delayed neurotoxicity -- hen	NA	NA	NA	Not required
81-8 (OPPTS 870.6200)	RIMON Technical: Neurotoxicity study by a single oral gavage administration to CD rats followed by a 14-day observation period.	45082601	Makhteshim-Agan of North America Inc.	OWN	
NONE (OPPTS 870.3050)	GR 572 (Technical): Toxicity to rats by dietary administration for 4 weeks.	45638313	Makhteshim-Agan of North America Inc.	OWN	



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DATA MATRIX

Date: April 12, 2010	EPA Reg. No./File Symbol 1 t678-57	Page of 18
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609	Product: RIMON® Technical	

Ingredient Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
81-8 (OPPTS 870.6200)	RIMON Technical: Neurotoxicity study by a single oral gavage administration to CD rats followed by a 14-day observation period.	45082601	Makhteshim-Agan of North America Inc.	OWN	
NONE (OPPTS 870.3050)	GR 572 (Technical): Toxicity to rats by dietary administration for 4 weeks.	45638313	Makhteshim-Agan of North America Inc.	OWN	
82-1 (OPPTS 870.3100)	"RIMON" Technical: Toxicity study by dietary administration to CD-1 Mice for 13 weeks followed by an 8 week reversibility period.	45651502	Makhteshim-Agan of North America Inc.	OWN	
82-1 (OPPTS 870.3100)	GR 572 (Technical): Toxicity to rats by dietary administration for 13 weeks.	45651503	Makhteshim-Agan of North America Inc.	OWN	
82-1 (OPPTS 870.3100)	GR 572 tech.: 13-week oral toxicity study in rats	45651504	Makhteshim-Agan of North America Inc.	OWN	
82-1 (OPPTS 870.3100)	Rimon Technical: Toxicity study by dietary administration to CD rats for 13 weeks Followed by a 4 week reversibility period.	45030001	Makhteshim-Agan of North America Inc.	OWN	
82-1 (OPPTS 870.3150)	"RIMON" Technical: Toxicity study by oral capsule administration to beagle dogs for 52 weeks.	45638320	Makhteshim-Agan of North America Inc.	OWN	
82-2 (OPPTS 870.3200)	"RIMON" Technical: Toxicity study by dermal administration to CD rats for 4 weeks.	45288501	Makhteshim-Agan of North America Inc.	OWN	
82-3 (OPPTS 870.3250)	90 day dermal	NA	NA	NA	Not required
82-4 (OPPTS 870.3465)	90 day inhalation - rat	NA	NA	NA	Not required
82-5	"Rimon" Technical: Neurotoxicity Study by Dietary Administration to CD Rats for 13 Weeks. Project Number: MAK/759/023152, R/14518, MAK/759.	46086204	Makhteshim-Agan of North America Inc.	OWN	
83-1 (OPPTS 870.4100)	"RIMON" Technical: Combined carcinogenicity and toxicity study by dietary administration to CD rats for 104 weeks...	45651506	Makhteshim-Agan of North America Inc.	OWN	



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DATA MATRIX

Date: April 12, 2010	EPA Reg. No./File Symbol 11678-57	Page of 18
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609	Product: RIMON® Technical	

Ingredient Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-2 (OPPTS 870.4200)	"RIMON" Technical: Carcinogenicity study by dietary administration to CD-1 mice for 78 weeks...	45651507	Makhteshim-Agan of North America Inc.	OWN	
83-3 (OPPTS 870.3700)	"RIMON" Technical: Preliminary study of embryo-foetal toxicity study in CD the rat by oral gavage administration...	45638315	Makhteshim-Agan of North America Inc.	OWN	
83-3 (OPPTS 870.3700)	"RIMON" Technical: Study of embryo-foetal toxicity in the CD rat by oral gavage administration...	45082602	Makhteshim-Agan of North America Inc.	OWN	
83-3 (OPPTS 870.3700)	Rimon Technical: Study of tolerance in the rabbit by oral gavage administration...	45638316	Makhteshim-Agan of North America Inc.	OWN	
83-3 (OPPTS 870.3700)	"RIMON" Technical: Preliminary embryo-foetal toxicity study in the rabbit by oral gavage administration...	45638317	Makhteshim-Agan of North America Inc.	OWN	
83-3 (OPPTS 870.3700)	"RIMON" Technical: Study of embryo-fetal toxicity in the rabbit by oral gavage administration...	45638318	Makhteshim-Agan of North America Inc.	OWN	
83-4 (OPPTS 870.3800)	"RIMON" Technical: Preliminary study of effects on reproductive performance in CD rats by dietary administration...	45638319	Makhteshim-Agan of North America Inc.	OWN	
83-4 (OPPTS 870.3800)	"RIMON" Technical: Study of reproductive performance in CD rats treated continuously through two successive generations by dietary administration...	45651505	Makhteshim-Agan of North America Inc.	OWN	
83-5 (OPPTS 870.4300)	"RIMON" Technical: Combined carcinogenicity and toxicity study by dietary administration to CD rats for 104 weeks...	45651506	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5100)	RIMON Technical: Bacterial mutation assay	44961013	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5140)	RIMON Technical: Bacterial mutation assay	44961013	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5250)	RIMON Technical: Bacterial mutation assay	44961013	Makhteshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5195)	In vitro assessment of the clastogenic activity of GR 572 in cultured human lymphocytes.	44961015	Makhteshim-Agan of North America Inc.	OWN	




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DATA MATRIX

Date: April 12, 2010			EPA Reg. No./File Symbol 11678-57	Page of 18	
Applicant/Registrant Name & Address: Makhateshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609			Product: RIMON® Technical		
Ingredient Novaluron					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
84-2 (OPPTS 870.5200)	In vitro assessment of the clastogenic activity of GR 572 in cultured human lymphocytes.	44961015	Makhateshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5300)	In vitro assessment of the clastogenic activity of GR 572 in cultured human lymphocytes.	44961015	Makhateshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5275)	GR 572 (FCF/T/46): Testing for mutagenic activity with <i>Salmonella typhimurium</i> TA 1535, TA 1537, TA 1538, TA 98 and TA 100 Inveresk.	45030003	Makhateshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5450)	GR 572 (FCF/T/46): Testing for mutagenic activity with <i>Salmonella typhimurium</i> TA 1535, TA 1537, TA 1538, TA 98 and TA 100 Inveresk.	45030003	Makhateshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5460)	GR 572 (FCF/T/46): Testing for mutagenic activity with <i>Salmonella typhimurium</i> TA 1535, TA 1537, TA 1538, TA 98 and TA 100 Inveresk.	45030003	Makhateshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5300)	An assessment of the mutagenic potential of GR 572 using the mouse lymphoma TK Locus Assay.	45638321	Makhateshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5395)	Mouse micronucleus test on GR 572.	45638322	Makhateshim-Agan of North America Inc.	OWN	
84-2 (OPPTS 870.5550)	"RIMON" Technical: Bacterial DNA repair (rec) assay.	44961014	Makhateshim-Agan of North America Inc.	OWN	

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Date: April 12, 2010		EPA Reg. No./File Symbol 11678-57
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609		Product: RIMON® Technical
Ingredient Novaluron		
Guideline Reference Number	Guideline Study Name	MRID Number
84-2 (OPPTS 870.5575)	"RIMON" Technical: Bacterial DNA repair (<i>rec</i>) assay.	44961014
84-2 (OPPTS 870.5500)	Assessment of unscheduled DNA repair synthesis in mammalian cells after exposure to GR 572.	45030002
84-2 (OPPTS 870.5550)	Assessment of unscheduled DNA repair synthesis in mammalian cells after exposure to GR 572.	45030002
84-2 (OPPTS 870.5575)	Assessment of unscheduled DNA repair synthesis in mammalian cells after exposure to GR 572.	45030002
84-4	Other genotoxic effects	NA
85-1 (OPPTS 870.7485)	¹⁴ C-"RIMON": Metabolism in the rat (Pilot Study)	45638323
85-1 (OPPTS 870.7485)	¹⁴ C-"RIMON": Metabolism in the rat	45638401
85-2 (OPPTS 870.7600)	Dermal penetration	NA
86-1	Domestic animal safety	NA

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DATA MATRIX

Date: April 12, 2010	EPA Reg. No./File Symbol 11678-57	Page of 18
Applicant's/Registrants Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609	Product: RIMON [®] Technical	

Ingredient Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Ecological Effects:					
71-1 (OPPTS 850.2100)	The acute oral toxicity (LD ₅₀) of GR 572 Technical to the Mallard Duck.	45499001	Makhteshim-Agan of North America Inc.	OWN	
71-1 (OPPTS 850.2100)	"Rimon" technical - Acute oral toxicity (LD ₅₀) to the Bobwhite quail (<i>Colinus virginianus</i>).	45476801	Makhteshim-Agan of North America Inc.	OWN	
71-2 (OPPTS 850.2200)	The dietary toxicity (LC ₅₀) of GR 572 to the Bobwhite quail.	45499002	Makhteshim-Agan of North America Inc.	OWN	
71-2 (OPPTS 850.2200)	The dietary toxicity (LC ₅₀) of GR 572 to the Mallard Duck.	45499003	Makhteshim-Agan of North America Inc.	OWN	
71-4 (OPPTS 850.2300)	"RIMON" technical: Reproduction in Bobwhite quail.	45638218	Makhteshim-Agan of North America Inc.	OWN	
71-4 (OPPTS 850.2300)	"RIMON" Technical: Reproduction in Mallard duck.	45638219	Makhteshim-Agan of North America Inc.	OWN	
72-1 (OPPTS 850.1075)	The acute toxicity of GR 572 Technical to Rainbow trout (<i>Salmo gairdneri</i>).	45499004	Makhteshim-Agan of North America Inc.	OWN	
72-1 (OPPTS 850.1075)	The acute toxicity of GR 572 Technical to Bluegill sunfish (<i>Lepomis macrochirus</i>).	45499005	Makhteshim-Agan of North America Inc.	OWN	
72-1 (OPPTS 850.1075)	275-352 I: Acute toxicity to Rainbow trout	45499006	Makhteshim-Agan of North America Inc.	OWN	
72-2 (OPPTS 850.1010)	"Rimon" technical: Acute toxicity to the <i>Daphnia magna</i> .	45476802	Makhteshim-Agan of North America Inc.	OWN	
72-2 (OPPTS 850.1010)	275-352 I: Acute toxicity to <i>Daphnia magna</i> .	45499007	Makhteshim-Agan of North America Inc.	OWN	
72-3 (OPPTS 850.1075)	Novaluron: Acute Toxicity to Sheepshead Minnow (<i>Cyprinodon variegatus</i>) Under Flow-Through Conditions.	45638210	Makhteshim-Agan of North America Inc.	OWN	
72-3 (OPPTS 850.1025) (draft guideline)	Novaluron: Acute Toxicity to Eastern Oyster (<i>Crassostrea virginica</i>) Under Flow-Through Conditions.	45638208	Makhteshim-Agan of North America Inc.	OWN	
72-3 (OPPTS 850.1035)	Novaluron: Acute Toxicity to Mysids (<i>Americamysis bahia</i>) Under Flow-Through Conditions.	45638209	Makhteshim-Agan of North America Inc.	OWN	
72-4 (OPPTS 850.1300)	¹⁴ C-"RIMON": <i>Daphnia magna</i> Reproduction test	45638211	Makhteshim-Agan of North America Inc.	OWN	
72-4 (OPPTS 850.1300)	(Carbon 14)-"Rimon": <i>Daphnia magna</i> Reproduction Test: Final Report. Project Number: MAK/405, MAK405/974265	46581401	Makhteshim-Agan of North America Inc.	OWN	
72-4 (OPPTS 850.1350)	Novaluron: Life Cycle Toxicity Test with Mysids (<i>Americamysis bahia</i>).	45638212	Makhteshim-Agan of North America Inc.	OWN	



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Date: April 12, 2010

EPA Reg. No./File Symbol 11678-57

Page of 18

Applicant's/Registrants Name & Address: Makteshim-Agan of North America Inc.
4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609

Product: RIMON[®] Technical

Ingredient	Novaluron
Water	100.00
NaOH	1.00
NaCl	1.00
Na ₂ SO ₄	1.00
Na ₂ CO ₃	1.00
Na ₂ HPO ₄	1.00
Na ₂ HPO ₄ ·7H ₂ O	1.00
Na ₂ HPO ₄ ·12H ₂ O	1.00
Na ₂ HPO ₄ ·2H ₂ O	1.00
Na ₂ HPO ₄ ·3H ₂ O	1.00
Na ₂ HPO ₄ ·4H ₂ O	1.00
Na ₂ HPO ₄ ·5H ₂ O	1.00
Na ₂ HPO ₄ ·6H ₂ O	1.00
Na ₂ HPO ₄ ·7H ₂ O	1.00
Na ₂ HPO ₄ ·8H ₂ O	1.00
Na ₂ HPO ₄ ·9H ₂ O	1.00
Na ₂ HPO ₄ ·10H ₂ O	1.00
Na ₂ HPO ₄ ·11H ₂ O	1.00
Na ₂ HPO ₄ ·12H ₂ O	1.00
Na ₂ HPO ₄ ·13H ₂ O	1.00
Na ₂ HPO ₄ ·14H ₂ O	1.00
Na ₂ HPO ₄ ·15H ₂ O	1.00
Na ₂ HPO ₄ ·16H ₂ O	1.00
Na ₂ HPO ₄ ·17H ₂ O	1.00
Na ₂ HPO ₄ ·18H ₂ O	1.00
Na ₂ HPO ₄ ·19H ₂ O	1.00
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Na ₂ HPO ₄ ·70H ₂ O	1.00
Na ₂ HPO ₄ ·71H ₂ O	1.00
Na ₂ HPO ₄ ·72H ₂ O	1.00
Na ₂ HPO ₄ ·73H ₂ O	1.00
Na ₂ HPO ₄ ·74H ₂ O	1.00
Na ₂ HPO ₄ ·75H ₂ O	1.00
Na ₂ HPO ₄ ·76H ₂ O	1.00
Na ₂ HPO ₄ ·77H	

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
72-4 (OPPTS 850.1400)	¹⁴ C-"RIMON" Technical: Fish early life stage toxicity test for Fathead minnow (<i>Pimephales promelas</i>).	45638213	Makhteshim-Agan of North America Inc.	OWN	
72-5 (OPPTS 850.1500)	Novaluron: Determination of effects on the reproduction of fathead minnow (<i>Pimephales promelas</i>).	45638214	Makhteshim-Agan of North America Inc.	OWN	
OPPTS 860.1135	(Carbon 14) "Rimon" to Assess the Toxicity to the Sediment Dwelling Phase of the Midge Chironomus riparius. Project Number: MAK/508, MAK/508/992185, R/10339.	46581402	Makhteshim-Agan of North America Inc.	OWN	
72-6 (OPPTS 850.1730)	¹⁴ C-"RIMON": Bioconcentration in Bluegill sunfish	45638215	Makhteshim-Agan of North America Inc.	OWN	
72-7 (OPPTS 850.1950)	Simulated or actual field testing – aquatic organisms	NA	NA	NA	Not required.



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Date: April 12, 2010	EPA Reg. No./File Symbol 11678-57	Page of 18
Applicant's/Registrants Name & Address: Makhleshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609	Product: RIMON® Technical	


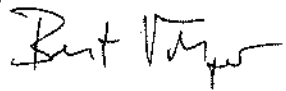
Ingredient Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Ecological Effects (Plant Protection):					
121-1 (OPPTS 850.4025)	Target Area phytotoxicity	NA	NA	NA	Not required
122-1 (OPPTS 850.4100)	Tier 1: Seed germination / seedling emergence	NA	NA	NA	Not required
122-1 (OPPTS 850.4150)	Tier 1: Vegetative vigor	NA	NA	NA	Not required
122-2 (OPPTS 850.4400)	Tier 1: Aquatic plant growth	NA	NA	NA	Not required
123-1 (OPPTS 850.4200)	Tier 2: Seed germination	NA	NA	NA	Not required
123-1 (OPPTS 850.4225)	Tier 2: Seedling emergence	NA	NA	NA	Not required
123-1 (OPPTS 850.4250)	Tier 2: Vegetative Vigor	NA	NA	NA	Not required
123-2 (OPPTS 850.5400)	"RIMON": Higher plant (<i>Lemna</i>) growth inhibition test	45638223	Makhleshim-Agan of North America Inc.	OWN	
123-2 (OPPTS 850.5400)	"RIMON" Technical: Algal growth inhibition assay	45638221	Makhleshim-Agan of North America Inc.	OWN	
123-2 (OPPTS 850.5400)	275-352 I: Algal growth inhibition assay. 45638221	45638222	Makhleshim-Agan of North America Inc.	OWN	
124-1 (OPPTS 850.4300)	Tier 3: Terrestrial field	NA	NA	NA	Not required
124-2 (OPPTS 850.4450)	Tier 3: Terrestrial – aquatic field	NA	NA	NA	Not required
					83

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DATA MATRIX					
Date: April 12, 2010		EPA Reg. No./File Symbol 11678-57	Page of 18		
Applicant's/Registrants Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609		Product: RIMON® Technical			
Ingredient Novaluron					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Ecological Effects (Nontarget Insects):					
141-1 (OPPTS 850.3020)	Rimon (Novaluron) Technical: Acute toxicity to honey bees (<i>Apis mellifera</i>)...	45638220	Makhteshim-Agan of North America Inc.	OWN	
141-2 (OPPTS 850.3030)	Honeybee – toxicity of residues on foliage	NA	NA	NA	Not required
141-4	Honeybee – subacute feeding study	NA	NA	NA	Not required
141-5 (OPPTS 850.3040)	Field testing for pollinators	NA	NA	NA	Not required
142-1	Acute toxicity to aquatic insects	NA	NA	NA	Not required
142-1	Aquatic insect life-cycle study	NA	NA	NA	Not required
142-3	Simulated or actual field testing for aquatic insects	NA	NA	NA	Not required
143-1 thru 143-3	Nontarget insect testing – predators and parasites	NA	NA	NA	Not required

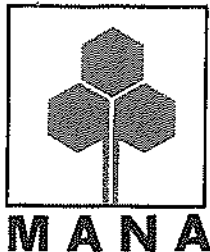
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DATA MATRIX					
Date: April 12, 2010		EPA Reg. No./File Symbol 11678-57	Page 18 of 18		
Applicant's/Registrants Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609		Product: RIMON® Technical			
Ingredient Novaluron					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Other Studies:					
NONE	"RIMON" Technical: Prolonged toxicity to Rainbow trout under flow-through conditions. 28 Day study.	45638216	Makhteshim-Agan of North America Inc.	OWN	
NONE	"Rimon" Technical: Acute toxicity (LC ₅₀) to the earthworm (<i>Eisenia foetida</i>).	45638224	Makhteshim-Agan of North America Inc.	OWN	
NONE	Chlorophenyl urea: Acute toxicity (LC ₅₀) to the earthworm (<i>Eisenia foetida</i>)	45638225	Makhteshim-Agan of North America Inc.	OWN	
NONE	Rimon Technical: Effects on soil non-target micro-organisms.	45638217	Makhteshim-Agan of North America Inc.	OWN	
NONE	Probabilistic Modeling of Novaluron Exposure to Aquatic Non-target Organisms and Drinking Water Associated with Use on Cotton and Apples.	45638402	Makhteshim-Agan of North America Inc.	OWN	
	Signature: 		Name and Title: Bert Volger, Ph.D., Consultant for Makhteshim-Agan of North America, Inc.		Date: 04/12/2010

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**Makhteshim-Agan of
North America, Inc.**

October 10, 2011

Office of Pesticide Programs (7505P)
US Environmental Protection Agency
Insecticide Rodenticide Branch
Registration Division
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Attention: John Hebert (RD – PM 07)

Subject: Rimon Technical (EPA Reg. No. 11678-57),
Submission of final printed label

Dear Mr. Hebert,

Pursuant to the recent label approval dated September 30, 2011 for the subject product, Makhteshim-Agan of North America Inc. would like to submit one copy of the final printed label (see enclosure) for your records before the release for shipment.

If you need any additional information or have any questions, please do not hesitate to contact me at 610 793 3222 or by e-mail: bertvolger@comcast.net.

Sincerely,

Bert Volger
Consultant for
Makhteshim-Agan of North America Inc



NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated

TECHNICAL

(Novaluron)

For The Manufacture of Insecticides Only

ACTIVE INGREDIENT: Novaluron:	% BY WT.
1-[3-chloro-4-(1,1, 2-trifluoro-2-trifluoromethoxyethoxy)phenyl]-	
3-(2, 6-difluorobenzoyl)urea.....	98.5%
OTHER INGREDIENTS:	1.5%
	TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact PROSAR at 1-877-250-9291 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters except in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

NET CONTENTS 55 POUNDS



EPA Reg. No. 1 t678-57
EPA Est. No. [REDACTED]

Page 1 of 3

Manufactured for:
Makhteshim Chemical Works, Ltd.
c/o Makhteshim-Agan of North America, Inc.
4515 Falls of Neuse Rd., Suite 300
Raleigh, NC 27609
919-256-9305

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This pesticide is for the further manufacture of formulated insecticides only. Formulators using this product are responsible for obtaining EPA registration for their formulated products.

Only for formulation into an insecticide for the following uses:

(1) Beans (snap, dry); Berries (low-growing), including cranberry, lingonberry, muntries, partridgeberry, bearberry, bilberry, lowbush blueberry, cloudberry; Bushberries, including: blueberry (highbush and lowbush), currant, elderberry, gooseberry, and huckleberry; Cotton; Cucurbit vegetables, including balsam apple, balsam pear, chayote (fruit) cantaloupe, cucumber, chinese cucumber, gherkin (west indian), edible gourd, melon, citron melon, muskmelon, bittermelon, pumpkin, squash, summer squash, winter squash, watermelon and chinese waxgourd; Fruiting vegetables (field grown), including tomatoes (including bush, currant and tree tomatoes), peppers, eggplants (including african, pea and scarlet eggplants), tomatillo, groundcherry, pepino, okra, cocona, goji berry, garden huckleberry, martynia, naranjilla, roselle, and sunberry; Head and stem brassica vegetables including: broccoli, chinese broccoli, brussel sprouts, cabbage, cavalo broccolo, cauliflower, chinese broccoli (gai lon), chinese cabbage (napa), chinese mustard (gai choy), and kohlrabi; Leafy brassica greens, including: broccoli raab, chinese cabbage (bok choy), collards, kale, mizuna, mustard greens, mustard spinach, and rape greens; Ornamentals (container grown ornamentals in green-houses, shade-houses, and outdoor nurseries); Pome fruit; Potatoes/ sweet potatoes; Stone fruits, including apricots, cherries (sweet and tart), nectarines, peaches, plums and prune plums; strawberry; sugarcane; sweet corn; Swiss chard; Turnip greens.

(2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and

(3) Uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

CONTAINER HANDLING:

Liner: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities.

Drum: Refillable container. Refill this container with novaluron only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. If drum is contaminated and can not be reused, dispose of in a sanitary landfill or by incineration if allowed by State and local authorities.

LIMITATION OF WARRANTY AND LIABILITY

Read the entire directions for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES and LIMITATIONS OF LIABILITY.**

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Makhteshim Chemical Works, Ltd. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Makhteshim Chemical Works, Ltd. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Makhteshim Agan of North America, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Makhteshim Chemical Works, Ltd. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Makhteshim Chemical Works, Ltd.'s election, the replacement of product.

Copyright 2002

RIMON[®] is a registered trademark of Makhteshim Chemical Works Ltd.

Rimon Technical (11678-57); (EPA approved 09-30-2011) final

Note To Jacket (1/10/2011)

The following e-mail is related to Decision # 421612, PP # 9F7630, explaining why the action was closed out after the PRIA due date passed.



PP 9F7630

Barbara Madden to: Jennifer Gaines
Cc: hebert.john

12/07/2009 03:55 PM

Jennifer,

John asked that I send you the following that should be filed in the petition jacket for the novaluron /egg action.

Summary as to why the PRIA date was missed:

1. There was a conditional data requirement for a poultry feeding study based on a previous review .
2. It was submitted/reviewed and as a result the egg tolerance needed to be increased . RD planned on increasing the tolerance with a FR that the MUT was preparing at the time the review was completed . However, this issue was raised to the RD PRIA committee and it was decided by Don Stubbs that since the conditional data resulted in a change of tolerance it was appropriate to charge a PRIA fee and require the registrant to submit a petition.
3. When the petition was submitted it wasn't processed correctly - a petition jacket was never made. Part of the problem was the way it was submitted. RD is not certain if we ever even saw the original package but we are not able to locate it. The registrant did not include a notice of filing , it was not formatted with the various subsections, the cover letter was vague, etc.
4. While trying to correct these omissions , the MUT proposed the tolerance increase in a Notice of Filing for a pending IR-4 petition.
5. RD always had it planned that we would just roll it in one of the novaluron IR-4 final rules. Laura Nollen recently completed work on one and publication is expected by mid- December. When Laura went to make reference to the egg petition in the Final Rule is when we realized that a petition jacket was never established. That's when the trouble started. Once the petition was set up it automatically was overdue . When this all began we may have been able to finish within the PRIA timeline for egg but there were delays with the novaluron joint review and the PRIA date had to be renegotiated.
6. Another funny thing. MANA paid the fee but because there was no petition, D-code (remember, this never got coded on the 4th floor), etc. the money was just sitting in an account earning interest. According to JJ we have \$1+ million sitting, not linked to any decisions. Apparently no one is trying to track down what this money should be linked to.

Material to be added to an e-Jacket/Jacket

Reg. No. 11678-57

Decision # _____

Description:

Please add the two enclosed final
printed labels to the jacket. Thank You

1. Placement within the e-Jacket/jacket:

☒ Default: (chronological, top = newest)

☐ File Location: (eg. "before page 45 in .pdf")

2. ☐ Send to Data Extraction contractors this material:

☐ Newly stamped accepted label

☐ Notification

☐ New CSF

☒ Other: Final Printed Labels

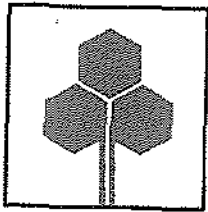
3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Jennifer Gaines

Phone: 305-5967

Division: RD

Date: 11/16/10



**Makhteshim Agan of
North America, Inc.**

M A N A

July 8, 2010

Office of Pesticide Programs (7505P)
US Environmental Protection Agency
Insecticide Rodenticide Branch
Registration Division
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Attention: John Hebert (RD – PM 07)

Subject: Rimon Technical (EPA Reg. No. 11678-57),
Rimon 0.83 EC (EPA Reg. No. 66222—35);
Submission of final printed labels

Dear Mr. Hebert,

Pursuant to the recent label approvals dated June 25, 2010 for the subject products, Makhteshim-Agan of North America Inc. would like to submit one copy of the final printed label for each product (see enclosure) before the release for shipment for your record. If you need any additional information or have any questions, please do not hesitate to contact me (610 793 3222).

Sincerely,

Bert Volger
Consultant for
Makhteshim-Agan of North America Inc



TECHNICAL

(Novaluron)

For The Manufacture of Insecticides Only

ACTIVE INGREDIENT: Novaluron:

% BY WT.

1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]-

3-(2,6-difluorobenzoyl)urea 98.5%

OTHER INGREDIENTS: 1.5%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID

IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact PROSAR at 1-877-250-9291 for emergency medical treatment information.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters except in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

NET CONTENTS 55 POUNDS



Manufactured for:
Makhteshim Chemical Works, Ltd.
c/o Makhteshim-Agan of North America, Inc.
4515 Falls of Neuse Rd., Suite 300
Raleigh, NC 27609
919-256-9946

EPA Reg. No. 11678-57

EPA Est. No. [REDACTED]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This pesticide is for the further manufacture of formulated insecticides only. Formulators using this product are responsible for obtaining EPA registration for their formulated products.

Only for formulation into an insecticide for the following uses:

- (1) Beans (snap, dry); Berries (low-growing), including cranberry, lingonberry, muntries, partridgeberry, bearberry, bilberry, lowbush blueberry, cloudberry; Bushberries, including: blueberry (highbush and lowbush), currant, elderberry, gooseberry, and huckleberry; Cotton; Cucurbit vegetables, including balsam apple, balsam pear, chayote (fruit) cantaloupe, cucumber, chinese cucumber, gherkin (west indian), edible gourd, melon, citron melon, muskmelon, bittermelon, pumpkin, squash, summer squash, winter squash, watermelon and chinese waxgourd; Fruiting vegetables (field grown), including tomatoes (including bush, currant and tree tomatoes), peppers, eggplants (including african, pea and scarlet eggplants), tomatillo, groundcherry, pepino, okra, cocona, goji berry, garden huckleberry, martynia, naranjilla, roselle, and sunberry; Head and stem brassica vegetables including: broccoli, chinese broccoli, brussel sprouts, cabbage, cavalo broccolo, cauliflower, chinese broccoli (gai lon), chinese cabbage (napa), chinese mustard (gai choy), and kohlrabi; Leafy brassica greens, including: broccoli raab, chinese cabbage (bok choy), collards, kale, mizuna, mustard greens, mustard spinach, and rape greens; Ornamentals (container grown ornamentals in green-houses, shade-houses, and outdoor nurseries); Pome fruit; Potatoes/ sweet potatoes; Stone fruits, including apricots, cherries (sweet and tart), nectarines, peaches, plums and prune plums; sorghum; strawberry; sugarcane; Swiss chard; Turnip greens.
- (2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- (3) Uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

CONTAINER HANDLING:

Liner: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities.

Drum: Refillable container. Refill this container with novaluron only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. If drum is contaminated and can not be reused, dispose of in a sanitary landfill or by incineration if allowed by State and local authorities.

LIMITATION OF WARRANTY AND LIABILITY

Read the entire directions for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES and LIMITATIONS OF LIABILITY.**

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Makhteshim Chemical Works, Ltd. All such risks shall be assumed by the user or buyer.

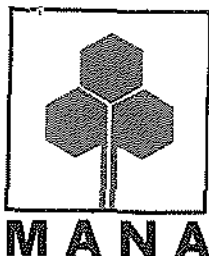
DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Makhteshim Chemical Works, Ltd. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Makhteshim Agan of North America, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Makhteshim Chemical Works, Ltd. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Makhteshim Chemical Works, Ltd.'s election, the replacement of product.

Copyright 2002

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Rimon Technical (11678-57); (EPA approved 06-25-2010)



**Makhteshim Agan of
North America, Inc.**

February 16, 2010

Office of Pesticide Programs (7505P)
US Environmental Protection Agency
Insecticide Rodenticide Branch
Registration Division
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Attention: Kable Bo Davis (RD – PM 07)

Subject: Rimon Technical (EPA Reg. No. 11678-57),
Rimon 0.83 EC (EPA Reg. No. 66222—35);
Submission of final printed labels

Dear Mr. Davis,

Pursuant to the recent label approvals dated February 12, 2010 for the subject products, Makhteshim-Agan of North America Inc. would like to submit one copy of the final printed label for each product (see enclosure) before the release for shipment for your record. If you need any additional information or have any questions, please do not hesitate to contact me (610 793 3222).

Sincerely,

Bert Volger
Consultant for
Makhteshim-Agan of North America Inc



NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated

TECHNICAL

(Novaluron)

FEB 12 2010

For The Manufacture of Insecticides Only

ACTIVE INGREDIENT: Novaluron:

% BY WT.

1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]-

3-(2,6-difluorobenzoyl)urea 98.5%

OTHER INGREDIENTS: 1.5%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID

IF ON SKIN OR CLOTHING:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

IF INHALED:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact PROSAR at 1-877-250-9291 for emergency medical treatment information.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters except in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

NET CONTENTS 55 POUNDS



EPA Reg. No. 11678-57

EPA Est. No. [REDACTED]

Page 1 of 3

Manufactured for:
Makhteshim Chemical Works, Ltd.
c/o Makhteshim-Agan of North America, Inc.
4515 Falls of Neuse Rd., Suite 300
Raleigh, NC 27609
919-256-9805

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This pesticide is for the further manufacture of formulated insecticides only. Formulators using this product are responsible for obtaining EPA registration for their formulated products.

Only for formulation into an insecticide for the following uses:

- (1) Beans (snap, dry); Berries (low-growing), including cranberry, lingonberry, muntries, partridgeberry, bearberry, bilberry, lowbush blueberry, cloudberry; Bushberries, including: blueberry (highbush and lowbush), currant, elderberry, gooseberry, and huckleberry; Cotton; Cucurbit vegetables, including balsam apple, balsam pear, chayote (fruit) cantaloupe, cucumber, chinese cucumber, gherkin (west indian), edible gourd, melon, citron melon, muskmelon, bittermelon, pumpkin, squash, summer squash, winter squash, watermelon and chinese waxgourd; Fruiting vegetables (field grown), including tomatoes (including bush, currant and tree tomatoes), peppers, eggplants (including african, pea and scarlet eggplants), tomatillo, groundcherry, pepino, okra, cocona, goji berry, garden huckleberry, martynia, naranjilla, roselle, and sunberry; Head and stem brassica vegetables including: broccoli, chinese broccoli, brussel sprouts, cabbage, cavalo broccolo, cauliflower, chinese broccoli (gai lon), chinese cabbage (napa), chinese mustard (gai choy), and kohlrabi; Leafy brassica greens, including: broccoli raab, chinese cabbage (bok choy), collards, kale, mizuna, mustard greens, mustard spinach, and rape greens; Ornamentals (container grown ornamentals in green-houses, shade-houses, and outdoor nurseries); Pome fruit; Potatoes/ sweet potatoes; Stone fruits, including apricots, cherries (sweet and tart), nectarines, peaches, plums and prune plums; Strawberry; Sugarcane; Swiss chard; Turnip greens.
- (2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- (3) Uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

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Drum: Refillable container. Refill this container with novaluron only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. If drum is contaminated and can not be reused, dispose of in a sanitary landfill or by incineration if allowed by State and local authorities.

LIMITATION OF WARRANTY AND LIABILITY

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DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Makhteshim Chemical Works, Ltd. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Makhteshim Agan of North America, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Makhteshim Chemical Works, Ltd. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Makhteshim Chemical Works, Ltd.'s election, the replacement of product.

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Rimon Technical (11678-57); EPA approved 02-12-2010 w comments incorporated



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11678-57	2. EPA Product Manager John Hebert	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Rimon® Technical (Novaluron)	PM# 07	
5. Name and Address of Applicant (Include ZIP Code) Makhteshim Chemical Works, Ltd. c/o MANA, Inc., 4515 Falls of Neuse Road, Suite 300 Raleigh, NC 27609 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated 01-29-09
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of Final Printed Labeling per EPA letter dated 01-29-09.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Christie Hitchcock		Title Regulatory Specialist		Telephone No. (Include Area Code) 919-256-9342	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Specialist			
4. Typed Name Christie Hitchcock		5. Date 08-14-09			



August 14, 2009

Document Processing Desk (FPL)
Registration Division (7504P)
OPP, USEPA
Ariel Rios Building
1200 Pennsylvania Ave, NW
Washington DC 20460

Attn: John Hebert
Product Manager 07
Insecticide-Rodenticide Branch
Registration Division (7505P)

Re: Submission of final printed labeling in response to EPA letter dated 01-29-09
Rimon® Technical (Novaluron) Insecticide; EPA Reg. No. 11678-57

Dear Mr. Hebert:

On behalf of Makhteshim Chemical Works, Ltd., Makhteshim Agan of North America, Inc. is submitting final printed labeling for the product referenced above in response to EPA letter dated 01-29-09.

In support of this request, the following documents for each product are enclosed:

- Application for Pesticide Registration (EPA Form 8570-1)
- One copy of the final printed label

Please contact me at 919-256-9342 or by email at chitchcock@manainc.com if you have any questions regarding this submission or would like a copy of the annotated label showing the changes for your files.

Sincerely,

Christie Hitchcock
Regulatory Specialist

Enclosures



NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated

TECHNICAL

(Novaluron)

JAN 29 2009

For The Manufacture of Insecticides Only

ACTIVE INGREDIENT: Novaluron:	% BY WT.
1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]-	
3-(2,6-difluorobenzoyl)urea	98.5%
INERT INGREDIENTS:	1.5%
	TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters except in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

NET CONTENTS 55 POUNDS



EPA Reg. No. 11678-57
EPA Est. No. [REDACTED]

Manufactured for:
Makhteshim Chemical Works, Ltd.
c/o Makhteshim-Agan of North America, Inc.
4515 Falls of Neuse Rd., Suite 300
Raleigh, NC 27609
919-256-9305

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This pesticide is for the further manufacture of formulated insecticides only. Formulators using this product are responsible for obtaining EPA registration for their formulated products.

Only for formulation into an insecticide for the following uses:

- (1) Ornamentals (greenhouses, shadehouses, and outdoor nurseries), cotton, pome fruits, potatoes, sweet potatoes, tomatoes, sugarcane, and head and stem brassica vegetables.
- (2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- (3) Uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

CONTAINER DISPOSAL: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

LIMITATION OF WARRANTY AND LIABILITY

Read the entire directions for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES and LIMITATIONS OF LIABILITY.**

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Makhteshim Agan of North America, Inc. All such risks shall be assumed by the user or buyer.

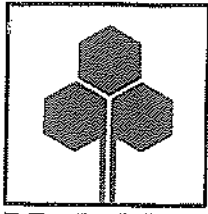
DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Makhteshim Agan of North America, Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Makhteshim Agan of North America, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Makhteshim Agan of North America, Inc. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Makhteshim Agan of North America, Inc.'s election, the replacement of product.

Copyright 2002

RIMON® is a registered trademark of Makhteshim Chemical Works Ltd.

Rimon Technical (11678-57)(EPA app 01-29-2009)



**Makhteshim Agan of
North America, Inc.**

M A N A

January 18, 2010

Office of Pesticide Programs (7505P)
US Environmental Protection Agency
Insecticide Rodenticide Branch
Registration Division
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Attention: Kable Bo Davis (RD – PM 07)

Subject: Rimon Technical (EPA Reg. No. 11678-57),
Rimon 0.83 EC (EPA Reg. No. 66222—35);
Submission of final printed labels

Dear Mr. Davis,

Pursuant to the recent label approvals dated December 30, 2009 for the subject products Makhteshim-Agan of North America Inc. would like to submit one copy of the final printed label for each product (see enclosure) for your record before the release for shipment. If you need any additional information or have any questions, please do not hesitate to contact me (610 793 3222).

Sincerely,

Bert Volger
Consultant for
Makhteshim-Agan of North America Inc



NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated

DEC 30 2009

TECHNICAL

(Novaluron)

For The Manufacture of Insecticides Only

ACTIVE INGREDIENT: Novaluron:	% BY WT.
1-[3-chloro-4-(1,1, 2-trifluoro-2-trifluoromethoxyethoxy)phenyl]-	
3-(2, 6-difluorobenzoyl)urea.....	98.5%
OTHER INGREDIENTS:	1.5%
	TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact PROSAR at 1-877-250-9291 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters except in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

NET CONTENTS 55 POUNDS



EPA Reg. No. 11678-57
EPA Est. No. [REDACTED]

Page 1 of 2

Manufactured for:
Makhteshim Chemical Works, Ltd.
c/o Makhteshim-Agan of North America, Inc.
4515 Falls of Neuse Rd., Suite 300
Raleigh, NC 27609
919 256-9300

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This pesticide is for the further manufacture of formulated insecticides only. Formulators using this product are responsible for obtaining EPA registration for their formulated products.

Only for formulation into an insecticide for the following uses:

- (1) Ornamentals (greenhouses, shadehouses, and outdoor nurseries), bushberry subgroup [Aronia berry; blueberry, highbush; blueberry, lowbush; buffalo currant; Chilean guava; cranberry, highbush; currant, black; currant, red; elderberry; European barberry; gooseberry; honeysuckle, edible; huckleberry; jostaberry; Juneberry (Saskatoon berry); lingonberry; native currant; salal; sea buckthorn; cultivars, varieties, and/or hybrids of these], cotton, leafy brassica greens, pome fruits, potatoes, stone fruits, sweet potatoes, tomatoes, sugarcane, and head and stem brassica vegetables, and turnip greens.
- (2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- (3) Uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

CONTAINER HANDLING:

Liner: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities.

Drum: Refillable container. Refill this container with novaluron only. Do not reuse this container for any other purpose. If drum is contaminated and cannot be reused, dispose of in a sanitary landfill or by incineration if allowed by State and local authorities.

LIMITATION OF WARRANTY AND LIABILITY

Read the entire directions for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES and LIMITATIONS OF LIABILITY.**

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Makhteshim Chemical Works, Ltd. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Makhteshim Chemical Works, Ltd. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Makhteshim Agan of North America, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Makhteshim Chemical Works, Ltd. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Makhteshim Chemical Works, Ltd.'s election, the replacement of product.

Copyright 2002

RIMON® is a registered trademark of Makhteshim Chemical Works Ltd.

Rimon Technical (11678-57)(EPA approved on 12-30-2009)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Bert Volger
Makhteshim Agan of North America, Inc.
4515 Falls of Neuse Rd., Suite 300
Raleigh, NC 27609

JUN 25 2010

Dear Mr. Volger:

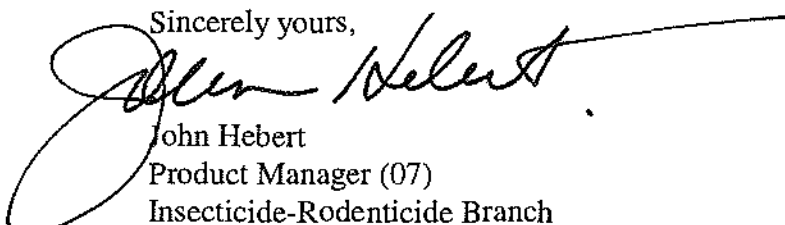
Subject: Label Amendment to Rimon Technical
EPA Registration No. 11678-57
Submission Date: March 16, 2009
OPP Decision Number: D-407898

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided you make the indicated label change and supply the following data requirements within twenty four (24) months of the date stamped on this label:

1. Storage stability data on grain sorghum forage, grain, aspirate grain fractions, and stover for up to 275, 253, 237, and 245 days, respectively (approximately 8 months).
2. Field studies at maximum proposed label rates (0.32 lb ai/A) using a crop attractive to bees must be conducted. This must be done according to EPA-approved protocols and examine the exposure and effects to honey bee adults and brood (Guideline 850.3040).
3. Since novaluron has outdoor uses, a seedling emergence study is required (Guideline 850.4100).
4. Since novaluron has outdoor uses, a vegetative vigor study is required (Guideline 850.4150).
5. Additionally, as noted on the December 30, 2009 letter, a submission of an immunotoxicity study is required within the timeframe specified in that letter (Guideline 870.7800).

A stamped copy is enclosed for your records. Please submit one (1) final printed copy for the above mentioned label before releasing the product for shipment. If you have any questions regarding this label, please contact Jennifer Gaines at (703) 305-5967.

Sincerely yours,


John Hebert
Product Manager (07)
Insecticide-Rodenticide Branch
Registration Division (7505P)



TECHNICAL

(Novaluron)

For The Manufacture of Insecticides Only

ACCEPTED
with COMMENTS
In EPA Letter Dated
JUN 25 2010
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
11678-57

ACTIVE INGREDIENT:	Novaluron:	% BY WT.
	1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]-	
	3-(2,6-difluorobenzoyl)urea.....	98.5%
OTHER INGREDIENTS:	1.5%
		TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

FIRST AID	
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IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact PROSAR at 1-877-250-9291 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS

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NET CONTENTS 55 POUNDS



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This pesticide is for the further manufacture of formulated insecticides only. Formulators using this product are responsible for obtaining EPA registration for their formulated products.

Only for formulation into an insecticide for the following uses:

(1) Beans (snap, dry); Berries (low-growing), including cranberry, lingonberry, muntries, partridgeberry, bearberry, bilberry, lowbush blueberry, cloudberry; Bushberries, including: blueberry (highbush and lowbush), currant, elderberry, gooseberry, and huckleberry; Cotton; Cucurbit vegetables, including balsam apple, balsam pear, chayote (fruit) cantaloupe, cucumber, chinese cucumber, gherkin (west indian), edible gourd, melon, citron melon, muskmelon, bittermelon, pumpkin, squash, summer squash, winter squash, watermelon and chinese waxgourd; Fruiting vegetables (field grown), including tomatoes (including bush, currant and tree tomatoes), peppers, eggplants (including african, pea and scarlet eggplants), tomatillo, groundcherry, pepino, okra, cocona, goji berry, garden huckleberry, martynia, naranjilla, roselle, and sunberry; Head and stem brassica vegetables including: broccoli, chinese broccoli, brussel sprouts, cabbage, cavalo broccolo, cauliflower, chinese broccoli (gai lon), chinese cabbage (napa), chinese mustard (gai choy), and kohlrabi; Leafy brassica greens, including: broccoli raab, chinese cabbage (bok choy), collards, kale, mizuna, mustard greens, mustard spinach, and rape greens; Ornamentals (container grown ornamentals in green-houses, shade-houses, and outdoor nurseries); Pome fruit; Potatoes/ sweet potatoes; Stone fruits, including apricots, cherries (sweet and tart), nectarines, peaches, plums and prune plums; sorghum; strawberry; sugarcane; Swiss chard; Turnip greens.

(2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and

(3) Uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

CONTAINER HANDLING:

Liner: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities.

Drum: Refillable container. Refill this container with novaluron only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. If drum is contaminated and can not be reused, dispose of in a sanitary landfill or by incineration if allowed by State and local authorities.

LIMITATION OF WARRANTY AND LIABILITY

Read the entire directions for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES and LIMITATIONS OF LIABILITY.**

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Makhteshim Chemical Works, Ltd. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Makhteshim Chemical Works, Ltd. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Makhteshim Agan of North America, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Makhteshim Chemical Works, Ltd. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Makhteshim Chemical Works, Ltd.'s election, the replacement of product.

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PRIA 2 - 21 Day Content Screen Review Worksheet

LRB/ pmf

(EPA/OPP Use Only) 4/9/08

21 Day Screen Start Date:

3/23/09

Date:

3/31/09

Experts In-Processing Signature:

Fee Paid: Yes ☒

Division management contacted on issues No ☐

Yes ☐

Date

EPA Reg. Number: 11678-57		EPA Receipt Date:				
Items for Review			Yes	No	N/A*	
1	Application Form (EPA Form 8570-1) signed & complete including package type			<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	a) All inerts, except fragrances, approved for food and non food proposed uses (see Footnote A)	Yes <input type="checkbox"/>	No <input type="checkbox"/>			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Certificate and data matrix consistent			<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	Yes <input type="checkbox"/>	No <input type="checkbox"/>			
	If applicable, is there a letter of Authorization for exclusive use only.			<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a) Selective Method (Fee category experts use)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>			
	b) Cite-All (Fee category experts use)	<input type="checkbox"/>	<input type="checkbox"/>			
	c) Applicant owns all data (Fee category experts use)	<input type="checkbox"/>	<input type="checkbox"/>			
6	3 Copies of Label (Electronic labels on CD are encouraged)			<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	Is the data package consistent with PR Notice 86-5			<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	Notice of Filing (link to included with petitions)			<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11678-57, 66222-35, 9F75472

9	If applicable for conventional applications, reduced risk rationale	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	Required Data and/or data waivers. See Footnote C.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	a) List study (or studies) not included with application			
<div> <div>Comments:</div> <div> <div>Date Start:</div> <div>Date End:</div> </div> </div>				

* N/A - Not Applicable

Footnotes

A. This consideration does not apply to PRIA applications that include a request to approve an inert in the fee category. For these PRIA actions, information needs to be submitted to enable the Agency to review the inert approval request and will be a subject of the 21 day content screen. For other types of actions and for fragrances, the answer is only for the Agency's information and current policies, processes, and procedures should be consulted. This worksheet will be updated in the future to be consistent with current policies.

If brand, trade, or proprietary names are being used for some inert ingredients listed on the CSF, alternate names or additional information on the nature of the ingredient(s) should be provided to allow the Agency to determine whether the inert has been approved.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Refer to the list of data requirements. Biopesticide applicants were advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 27, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-407898
EPA File Symbol or Registration Number: 11678-57
Product Name: RIMON TECHNICAL
EPA Receipt Date: 23-Mar-2009
EPA Company Number: 11678
Company Name: MAKHTESHIM CHEMICAL WORKS LTD

Bert Volger
MAKHTESHIM-AGAN OF NORTH AMERICA, INC.
MAKHTESHIM CHEMICAL WORKS LTD
4515 FALLS OF NEUSE RD, SUITE 300
RALEIGH, NC 27609-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

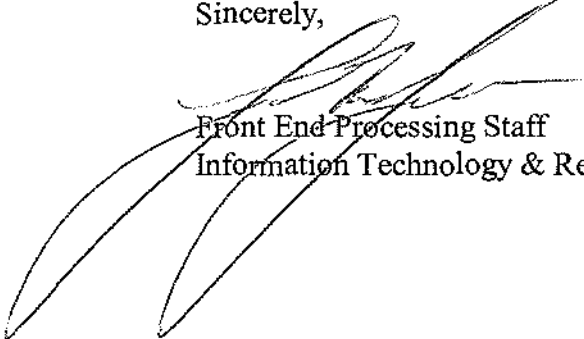
The Action has been identified as Action Code: R170

NEW USE;EACH ADDITIONAL NEW FOOD USE;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-6249.

Sincerely,


Front End Processing Staff
Information Technology & Resources Management Division

Revised

Fee for Service

{847026'~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 7

Receipt No.

S- 847026

EPA File Symbol/Reg. No.

11678-57

Pin-Punch Date:

3/23/2009

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R180

Granted: R170.00

Amount Due: \$ 57,120.00

Parent/Child Decisions:

9F7547 (S 847024)

66222-35
(S 847025)

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: *[Signature]*

Date: 3-25-09

Remarks:

- Not R180; reduced risk request not submitted
OK
- new tolerance; Sorghum

Receipt for Section 3

S: 847026

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 11678 MAKHTESHIM CHEMICAL WORKS LTD

V

Risk Manager: Registration Division, Risk Management Team 7

Product #: 11678-57 Product Name: RIMON TECHNICAL

Overlaid:

Me Too

Me Too

Section3:

Product Name:

Application Date: 16-Mar-2009

ic

OPP Rec'd Date: 23-Mar-2009

ic

Front End Date: 23-Mar-2009

ic

Risk Manager Send Date:

ic

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Petition of tolerances and adding new food use (sorghum)

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des


Study

Paper Label

View/Edit

Total		57,120.00		57,120.00
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ORIGINAL CHECK HAS A COLORED BACKGROUND PRINTED ON CHEMICAL REACTIVE PAPER



MAKHTESHIM AGAN OF NORTH AMERICA, INC.
4515 Falls of Neuse Road, Suite 300
Raleigh, NC 27609

bank leumi USA

Member FDIC
564 FIFTH AVENUE
NEW YORK, NY 10036
1-279/260

032303

DATE
03/19/09

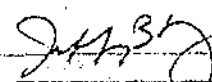
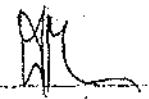
CHECK NO
32303

Fifty-seven thousand one hundred and twenty Dollars and 00 Cent

PAY
TO THE
ORDER OF

U.S. EPA

AMOUNT
***USD 57,120 00

MP

RED CHECK NUMBERING IMAGES THROUGH TO BACK OF SHEET

⑈032303⑈ ⑆028002794⑆



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11678-57	2. EPA Product Manager John Hebert	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) RIMON TECHNICAL	PM# 07	
5. Name and Address of Applicant (Include ZIP Code) Makhteshim Chemical Works c/o Makhteshim Agan of North America, Inc. 4515 Falls of Neuse Rd, Suite 300 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional sheets if necessary. (For section I and Section II.)

Petition of tolerances and adding new food use (sorghum). Submission of data to support this application (Reduced Risk).

FEE CATEGORY: R180: 10 month review process

FEE DUE: \$ 57,120

EMAIL: bertvolger@comcast.net

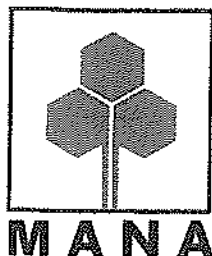
Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container	<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Bert Volger		Title Consultant for MANA		Telephone No. (Include Area Code) 610-793-3222	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Consultant for MANA			
4. Typed Name Bert Volger		5. Date 03/16/2009			

119



**Makhteshim-Agan of
North America, Inc.**

March 19, 2009
Delivered by Courier

Document Processing Desk - H7504P
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Mr. John Hebert – PM 07

Dear Mr. Hebert,

**Subject: Novaluron (Chemical Code 124002, EPA Reg. No. 11678-57)
Petition for Establishment of Tolerance for Novaluron in or on
the Processed Commodities: Grain Sorghum – Grain, Aspirated
Grain Fractions, Forage and Stover**

Makhteshim-Agan of North America Inc. (MANA), acting as the registered US Agent for Makhteshim Chemical Works (MCW), submits this petition pursuant to Section 408 (d)(1) of the Federal Food, Drug, and Cosmetic Act with respect to the insecticide novaluron to amend 40 CFR180.

The subject petition compliments the recently submitted petition for novaluron residues in or on Vegetables, Cucurbit; Vegetables, Fruiting; Beans (Dry); Beans (Snap, Succulent); Low Growing Berries; Swiss Chard (PP# to be assigned), which was submitted by the IR-4 on March 17, 2009.

Enclosed you will find all necessary data and information to establish a tolerance for novaluron residues in or on Grain Sorghum (Grain, Aspirated Grain Fractions, Forage and Stover) and the request for raising the existing livestock tolerances for residues of novaluron in or on poultry, fat to 7.0 ppm; poultry, meat to 0.4 ppm; poultry, meat byproducts to 0.8 ppm; hog, fat to 1.5 ppm; hog, meat to 0.07 ppm; hog, meat byproducts to 0.15 ppm; and eggs to 1.5 ppm.

Three (3) hard copies of the following documents are enclosed (see also attached bibliography of submitted studies for more details):

- **Volume 1 of 2 (Administrative Volume):** Petition for Establishment of Tolerance and Method of Support for the Tolerance including a copy of a Notice of Filing entitled "Publicly Releasable Summary of the Petition for Establishment of a Tolerance for Novaluron in or on Vegetables, Cucurbit; Vegetables, Fruiting; Beans (Dry); Beans (Snap, Succulent); Low Growing Berries; Swiss Chard and Sorghum". This document will also be submitted separately as a paper copy and an electronic file, attached to MANA's consent letter regarding the Agency's publication of this document in the Federal Register.
- **Volume 2 of 2:** Residue Data (Magnitude of Residues, OPPTS Ref. 860.1000, 860.1340, 860.1380, 860.1500, and 860.1520) to support the subject Tolerance Petition.

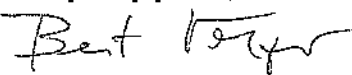
In addition, there are the following materials:

- Bibliography of Submitted Studies.
- EPA Form 8570-1 (Rev. 3-94): An executed "Application for Pesticide Registration" for each product (Rimon 0.83 EC - EPA Reg. No. 66222-35, and Rimon Technical - EPA Reg. No. 11678-57).
- Proposed Label (3 copies) for the use of Rimon 0.83 EC on sorghum (Also included in Section B of the Petitions (Administrative Volume).
- Proposed label (3 copies) for the use of Rimon Technical on sorghum.
- EPA Form 8570-34 Certification with Respect to Proper Citation of Data for the formulated product and the technical material.
- EPA Form 8570-35 for the formulated product and the technical material (Agency and Public Use Copy).
- Payment of PRIA fee for \$57,120 (EPA category R180 - additional food use (reduced risk) and increase existing livestock tolerances). Attached is a copy of the submitted check (MANA - #032303). A check in this amount was sent by USPS to:
U.S. Environmental Protection Agency
Washington Finance Center
FIFRA Service Fees
P.O. Box 979074
St. Louis, MO 63197-9000

It is our understanding that this petition will be reviewed concurrently with the IR-4 petition for novaluron residues in or on in or on Vegetables, Cucurbit; Vegetables, Fruiting; Beans (Dry); Beans (Snap, Succulent); Low Growing Berries; Swiss Chard submitted on March 17, 2009.

If you have any question or need further information regarding this petition, please fee free to contact me at 212-896-4945 or Bert Volger at 610-793-3222

Very truly yours,


for Robert C. Everich, Ph.D.
Senior Scientist
Makhteshim-Agan of North America Inc.

BIBLIOGRAPHY OF SUBMITTED STUDIES

Name and Address of Submitter: Dr. Robert Everich
Senior Scientist
Makhteshim-Agan of North America Inc.
4515 Falls of Neuse Road, Suite 300
Raleigh, NC 27609

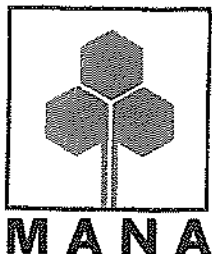
Product(s): Rimon® 10EC (Novaluron)

EPA Reg.No: 66222-35

Purpose of Submission: Submission of Field Residue Data in Support of a Petition for
Establishment of Tolerance in or on Grain Sorghum

Date of Submission: March 19, 2009

Volume Number	Study Title	Submitter Document Number	EPA/OPPTS Guidelines Reference Number	EPA MRID Number (Reserved for EPA Use)
1 of 2	Petition for Establishment of Tolerance and Method of Support for Novaluron Grain Sorghum	MANA-090316	N/A	
2 of 2	Magnitude of the Residue of Novaluron in Grain Sorghum Raw Agricultural and Processed Commodities	MANA R-22800	860.1000, 860.1340, 860.1380, 860.1500, and 860.1520	



**Makhteshim-Agan of
North America, Inc.**

March 16, 2009

Document Processing Desk (IR-4)
Office of Pesticide Programs (H7505C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW.
Washington, DC 20460-0001

Attn: Mr. John Hebert – PM 07

Dear Mr. Hebert,

Subject: Novaluron (Chemical Code 124002), EPA Reg. No. 11678-57,
Publicly Releasable Summary regarding FQPA Compliance to Support the
Petition (PP# not assigned) for Establishment of a Tolerance for Novaluron in
or on Vegetables, Cucurbit; Vegetables, Fruiting; Beans (Dry); Beans (Snap,
Succulent); Low Growing Berries; Swiss Chard and Sorghum

Makhteshim-Agan of North America Inc. (MANA), the basic registrant of novaluron, and the Interregional Research Project Number 4 (IR-4) submitted petitions for the establishment of the above mentioned tolerance for residues of novaluron. MANA prepared the publicly releasable summary of compliance with the Food Quality Protection Act of 1996 (FQPA) in support of the subject petition (see enclosure). This document is titled:

"Publicly Releasable Summary of the Petition for Establishment of a Tolerance for Novaluron in or on Vegetables, Cucurbit; Vegetables, Fruiting; Beans (Dry); Beans (Snap, Succulent); Low Growing Berries; Swiss Chard and Sorghum"

We are giving our consent for EPA to publish this summary of compliance with FQPA in the Federal Register. Attached you will find a paper copy, as well as an electronic copy containing the subject summary (see enclosed diskette, Word-file)

If you have any questions regarding this summary or the subject petition, please contact me under 212-896-4945 or Bert Volger at 610-793-3222.

Very truly yours,

for Robert C. Everich, Ph.D.
Senior Scientist
Makhteshim-Agan of North America Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Makhteshim-Agan North America Inc., 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609	EPA Registration Number/File Symbol 11678-57
Active Ingredient(s) and/or representative test compound(s) Novaluron	Date March 16, 2009
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Insecticide for use on ornamentals, bushberries, cotton, leafy brassica greens, peaches, pome fruit	Product Name RIMON TECHNICAL

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 03/16/2009	Typed or Printed Name and Title Bert Volger Ph.D., Consultant to MANA
---------------	--------------------	--



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: March 16, 2009	EPA Reg. No./File Symbol 66222-35	Page 1 of 6
Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609	Product: RIMON® 0.83EC Insecticide	

Ingredient Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Physical and Chemical Properties:					
158.155 (OPPTS 830.1550)	"Rimon 10EC": OPPTS 830 Series Subgroup A Product Chemistry.	44964507	Makhteshim-Agan of North America Inc.	OWN	
158.160 (OPPTS 830.1600)	"Rimon 10EC": OPPTS 830 Series Subgroup A Product Chemistry.	44964507	Makhteshim-Agan of North America Inc.	OWN	
158.165 (OPPTS 830.1650)	"Rimon 10EC": OPPTS 830 Series Subgroup A Product Chemistry.	44964507	Makhteshim-Agan of North America Inc.	OWN	
158.167 (OPPTS 830.1670)	"Rimon 10EC": OPPTS 830 Series Subgroup A Product Chemistry.	44964507	Makhteshim-Agan of North America Inc.	OWN	
158.175 (OPPTS 830.1750)	"Rimon 10EC": OPPTS 830 Series Subgroup A Product Chemistry.	44964507	Makhteshim-Agan of North America Inc.	OWN	
158.180 (OPPTS 830.1800)	"RIMON" 10EC: Accelerate storage stability	44964509	Makhteshim-Agan of North America Inc.	OWN	
63-2 (OPPTS 830.6302)	"RIMON" 10EC: Determination of the physico-chemical properties	44964510	Makhteshim-Agan of North America Inc.	OWN	
63-3 (OPPTS 830.6303)	"RIMON" 10EC: Determination of the physico-chemical properties	44964510	Makhteshim-Agan of North America Inc.	OWN	
63-7 (OPPTS 830.7300)	"RIMON" 10EC: Determination of the physico-chemical properties	44964510	Makhteshim-Agan of North America Inc.	OWN	
63-12 (OPPTS 830.7000)	"RIMON" 10EC: Determination of the physico-chemical properties	44964510	Makhteshim-Agan of North America Inc.	OWN	
63-13 (OPPTS 830.6313)	"RIMON" 10EC: Accelerate storage stability	44964509	Makhteshim-Agan of North America Inc.	OWN	
63-14 (OPPTS 830.6314)	"RIMON" 10EC: Determination of the physico-chemical properties	44964510	Makhteshim-Agan of North America Inc.	OWN	



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401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: March 16, 2009

EPA Reg. No./File Symbol 66222-35

Page 2 of 6

Applicant/Registrant Name & Address: Makhteshim-Agan of North America Inc.
 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609

Product: RIMON® 0.83EC Insecticide

Ingredient Novaluron

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
63-14 (OPPTS 830.6314)	"RIMON" 10EC: Determination of the physico-chemical properties	44964508	Makhteshim-Agan of North America Inc.	OWN	
63-15 (OPPTS 830.6315)	"RIMON" 10EC: Determination of the physico-chemical properties	44964510	Makhteshim-Agan of North America Inc.	OWN	
63-16 (OPPTS 830.6316)	"RIMON" 10EC: Determination of the physico-chemical properties	44964510	Makhteshim-Agan of North America Inc.	OWN	
63-17 (OPPTS 830.6317)	"RIMON" 10EC: Storage stability	44964511	Makhteshim-Agan of North America Inc.	OWN	
63-18 (OPPTS 830.7100)	"RIMON" 10EC: Determination of the physico-chemical properties	44964510	Makhteshim-Agan of North America Inc.	OWN	
63-19 (OPPTS 830.6319)	"RIMON" 10EC: Determination of the physico-chemical properties	44964510	Makhteshim-Agan of North America Inc.	OWN	
63-20 (OPPTS 830.6320)	"RIMON" 10EC: Storage stability	44964511	Makhteshim-Agan of North America Inc.	OWN	
63-21 (OPPTS 830.6321)	"RIMON" 10EC: Determination of the physico-chemical properties	44964510	Makhteshim-Agan of North America Inc.	OWN	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: March 16, 2009			EPA Reg. No./File Symbol 66222-35	Page 3 of 6	
Applicant's/Registrants Name & Address Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609			Product: RIMON® 0.83EC Insecticide		
Ingredient Novaluron					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Residue Chemistry:					
171-4 (OPPTS 860.1500)	Magnitude of the Residue of Novaluron in Cotton Raw Agricultural and Processed Commodities.	45638412	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1500)	Magnitude of the Residue of Novaluron in Cotton Raw Agricultural Commodities - Bridging Study: Final Study Report. Project Number: AA020705, R/15424, AR1	46086205	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1500)	Magnitude of the Residue of Novaluron in Cotton Raw Agricultural and Processed Commodities: Amended Final Study Report. Project Number: AA990801/AZ1, AA990801/CA1, AA990801/CA2.	46141001	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1500)	Residue Decline Curve Study with "Rimon" 10EC Applied to Potatoes in Germany, Spain and Italy	45771801	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1500)	Raw Agricultural Commodity and Residue decline Curve Study with "Rimon" 10EC Applied Potatoes in Germany, Northern and Southern France, Spain and Italy	45771802	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1500)	Magnitude of the Residue of Novaluron in Pome Fruit Raw Agricultural Commodities - Formulation Bridging Study: Final Report. Project Number: AA040703, R/17287, 2005/1.	46512101	Makhteshim-Agan of North America Inc.	OWN	
171-4 (OPPTS 860.1500)	Magnitude of the Residue of Novaluron in Sugarcane Raw Agricultural and Processed Commodities: Final Report. Project Number: AA050701, R/18186, FL1.	46819601	Makhteshim-Agan of North America Inc.	OWN	

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Agency Internal Use Copy



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401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: March 16, 2009			EPA Reg. No./File Symbol 66222-35	Page 4 of 6	
Applicant's/Registrants Name & Address Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609			Product: RIMON® 0.83EC Insecticide		
Ingredient Novaluron					
171-4 (OPPTS 860.1500)	Magnitude of the Residue on Tomato. Project Number: 08419,04/PTR02	47094901	IR-4	PER	
171-4 (OPPTS 860.1500)	Novaluron on cabbage: Magnitude of the Residue Study. Project No. 1308W, RP/04013, RIM/232	47180501	Makhteshim-Agan of North America Inc.	OWN	
164-1 (OPPTS 835.6100)	Terrestrial Field Soil Dissipation of Novaluron. American Agricultural Services, Inc. Cary, N.C...	45789204	Makhteshim-Agan of North America Inc.	OWN	
164-1 (OPPTS 835.6100)	Terrestrial Field Soil Dissipation of Novaluron: Amended Final Study Report. Project Number: AA010702, R/13885, 20/01/099.	46086202	Makhteshim-Agan of North America Inc.	OWN	
164-1 (OPPTS 835.6100)	Terrestrial Field Dissipation Study with "Rimon" 10EC Applied to Bare Soil in Spain and Germany	45638403	Makhteshim-Agan of North America Inc.	OWN	
81-1 (OPPTS 870.1100)	"Rimon" 10EC: Acute oral toxicity to rat	44964501	Makhteshim-Agan of North America Inc.	OWN	
81-2 (OPPTS 870.1200)	"Rimon" 10EC: Acute dermal toxicity to rat	44964502	Makhteshim-Agan of North America Inc.	OWN	
81-3 (OPPTS 870.1300)	"Rimon" 10EC: Acute inhalation toxicity to the rat	NA	NA	NA	Waiver approved
81-4 (OPPTS 870.2400)	Primary Eye irritation/Corrosion test of "RIMON" 10EC in Rabbits	44964503	Makhteshim-Agan of North America Inc.	OWN	
81-4 (OPPTS 870.2400)	"RIMON" 10EC (0.1% v/v field dilution): Eye irritation to rabbit	45638414	Makhteshim-Agan of North America Inc.	OWN	



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DATA MATRIX

Date: March 16, 2009			EPA Reg. No./File Symbol 66222-35	Page 5 of 6	
Applicant's/Registrants Name & Address Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609			Product: RIMON® 0.83EC Insecticide		
Ingredient Novaluron					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
81-5 (OPPTS 870.2500)	"Rimon" 10EC: Skin irritation to the rabbit	44964504	Makhteshim-Agan of North America Inc.	OWN	
81-6 (OPPTS 870.2600)	"RIMON" 10EC – Skin sensitisation in the Guinea-pig (incorporating a positive control using hexyl cinnamic aldehyde)	44964505	Makhteshim-Agan of North America Inc.	OWN	
81-6 (OPPTS 870.2600)	"RIMON" 10EC – Skin sensitisation in the Guinea-pig (Buehler method – 9 inductions incorporating a positive control using hexyl cinnamic aldehyde)	44964506	Makhteshim-Agan of North America Inc.	OWN	
85-3 (OPPTS 870.7600)	14C-"RIMON" 10EC: In vivo dermal penetration study in the male rat. Report No. MAK 577/002095. MCW Report No. R-11140	45638415	Makhteshim-Agan of North America Inc.	OWN	
Reentry Protection Data Requirements:					
132-1 (OPPTS 875.2100)	Foliar Dislodgeable Residues Dissipation of Novaluron in Cotton	45638416	Makhteshim-Agan of North America, Inc.	OWN	
Ecological Effects:					
72-1 (OPPTS 850.1075)	"Rimon" 10EC: Acute toxicity to Rainbow trout	45638314	Makhteshim-Agan of North America Inc.	OWN	
72-2 (OPPTS 850.1010)	"Rimon" 10EC: Acute toxicity to Daphnia magna	45638413	Makhteshim-Agan of North America Inc.	OWN	

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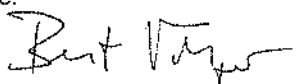


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Date: March 16, 2009			EPA Reg. No./File Symbol 66222-35	Page 6 of 6	
Applicant's/Registrants Name & Address Makhteshim-Agan of North America Inc. 4515 Falls of Neuse Road, Suite 300, Raleigh, NC 27609			Product: RIMON® 0.83EC Insecticide		
Ingredient Novaluron					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
72-6 (OPPTS 850.1730)	An assessment of the bioconcentration of "Rimon 10EC" in Rainbow trout in a mesocosm	45638405	Makhteshim-Agan of North America Inc.	OWN	
N/A	"Rimon" 10EC: Prolonged toxicity to Rainbow trout underflow-through conditions 28-day study	45638406	Makhteshim-Agan of North America Inc.	OWN	
N/A	Evaluation of the effects of "RIMON" 10 EC on populations of non-target arthropods in citrus groves.	45638410	Makhteshim-Agan of North America Inc.	OWN	
72-3 (OPPTS 850.1025)	Rimon 10 EC: Mysid Acute Toxicity Test. Project Number: MAK/783, MAK/783/032052.	46086203	Makhteshim-Agan of North America Inc.	OWN	
Ecological Effects (Nontarget Ins. & Plants):					
141-1 (OPPTS 850.3020)	"RIMON" 10EC: Evaluation of the effects of insect growth-regulating insecticides on honey bee (Apis mellifera) colony brood development.	45638407	Makhteshim-Agan of North America Inc.	OWN	
141-5 (OPPTS 850.3040)	Novaluron: Evaluation of the effects of "RIMON" 10EC on populations of non-target arthropods in citrus groves.	45638410	Makhteshim-Agan of North America Inc.	OWN	
123-2 (OPPTS 850.5400)	"RIMON": 10EC Algal growth inhibition survey	45638411	Makhteshim-Agan of North America Inc.	OWN	
	Signature: 		Name and Title: Bert Volger, Ph.D., Consultant for Makhteshim-Agan of North America, Inc.		Date: 03-16-2009

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